

EXHIBIT “A”

Deposition Transcript of Anatoly Aleksandrovich (May 18, 2018)

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

- - -

GARY BRYAN BRACKIN,	:	CIVIL ACTION
Individually and in his	:	
capacity as Surviving	:	
Spouse of PAMELA W.	:	
BRACKIN, deceased,	:	
Plaintiff,	:	
	:	NO.
v.	:	2:17-cv-2101
	:	
MEDTRONIC, INC., et al.,	:	
Defendants.	:	

STATE OF MINNESOTA
COUNTY OF HENNEPIN - FOURTH JUDICIAL DISTRICT

CHARLES EKLUND,	:	
Plaintiff,	:	
	:	
v.	:	
	:	
MEDTRONIC, INC., a	:	NO.
Minnesota corporation;	:	27-CV-17-18038
MEDTRONIC MINIMED, a	:	
Division of MEDTRONIC,	:	
INC.; UNOMEDICAL DEVICES	:	
S.A. de C.V., and	:	
UNOMEDICAL A/S,	:	
Defendants.	:	

- - -

May 18, 2018

DEPOSITION OF ANATOLY ALEKSANDROVICH

- - -

Anatoly Aleksandrovich

1 2 Videotaped teleconferenced 3 deposition of ANATOLY ALEKSANDROVICH taken 4 pursuant to notice, was held at 16501 Ventura 5 Boulevard Suite 400 Encino, California, beginning 6 at 9:46 a.m., on the above date, before Ann Marie 7 Mitchell, a Federally Approved Certified Realtime 8 Reporter, Registered Diplomat Reporter and 9 Notary Public. 10 11 12 13 14 15 16 17 18 19 - - - 20 21 22 GOLKOW LITIGATION SERVICES 23 877.370.3377 ph 917.591.5672 24 deps@golkow.com	Page 2 1 APPEARANCES (cont'd): 2 3 MASLON LLP 4 BY: NICOLE E. NAROTZKY, ESQUIRE 5 3300 Wells Fargo Center 6 90 South Seventh Street 7 Minneapolis, Minnesota 55402 8 (612) 672-8200 9 nicole.narotzky@maslon.com 10 Representing Medtronic 11 12 THOMPSON HINE LLP 13 BY: Z. ILEANA MARTINEZ, ESQUIRE 14 Two Alliance Center 15 3560 Lenox Road NE, Suite 1600 16 Atlanta, Georgia 30326 17 (404) 541-2900 18 ileana.martinez@thompsonhine.com 19 Representing Unomedical A/S in the Eklund 20 Litigation 21 22 VIDEOGRAPHER: 23 DAVID KIM 24
Page 3 1 APPEARANCES: 2 WILLIAMS CEDAR LLC 3 BY: KEVIN HAVERTY, ESQUIRE 4 1515 Market Street 5 Suite 1300 6 Philadelphia, Pennsylvania 19103 7 (215) 557-0099 8 khaverty@williamscedar.com 9 Representing the Brackin Plaintiffs 10 GARY K. SMITH LAW FIRM, PLLC 11 BY: PHILIP M. CAMPBELL, ESQUIRE 12 The Forum III 13 1770 Kirby Parkway, Suite 427 14 Memphis, Tennessee 38138 15 (901) 308-6484 16 pcampbell@garyksmithlaw.com 17 Representing the Brackin Plaintiffs 18 GOLDENBERG LAW, PLLC 19 BY: MARLENE GOLDENBERG, ESQUIRE 20 800 Lasalle Avenue 21 Suite 2150 22 Minneapolis, Minnesota 55402 23 (855) 975-6581 24 mjgoldenberg@goldenberglaw.com 25 Representing the Eklund Plaintiffs 26 GREENBERG TRAURIG, LLP 27 BY: CLIFF MERRELL, ESQUIRE 28 3333 Piedmont Road, NE 29 Suite 2500 30 Atlanta, Georgia 30305 31 (678) 553-2100 32 merrellc@gtlaw.com 33 Representing Medtronic	Page 5 1 - - - 2 I N D E X 3 - - - 4 5 Testimony of: ANATOLY ALEKSANDROVICH 6 By Mr. Haverty 14, 323 7 By Mr. Merrell 308 8 By Ms. Martinez 320 9 By Ms. Goldenberg 329 10 11 E X H I B I T S 12 13 NO. DESCRIPTION PAGE 14 AA-1 Slide, "P-cap Infusion Sets 104 15 Prime Fill Anomaly CAPA 16 PR#158416," Bates stamped 17 MDT-BRACP-029894 18 AA-2 CAPA Full Detail Report with 62 19 five Family Tree Levels - 20 PDF, Bates stamped 21 MDT-BRACP-028983 through 22 MDT-BRACP-029065 23 AA-6 Video file 56 24 AA-8 PowerPoint, "Prime/Fill 79 25 Anomaly Review 3-21-13," 26 Bates stamped 27 MDT-BRACP-0067966 through 28 MDT-BRACP-0067973

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1 - - - 2 DEPOSITION SUPPORT INDEX 3 - - - 4 5 Direction to Witness Not to Answer 6 7 Page Line 8 9 Request for Production of Documents 10 Page Line 11 12 13 14 Stipulations 15 Page Line 16 17 18 Question Marked 19 Page Line 20 21 22 23 24	1 I just wanted to note for the record that 2 while I don't believe that there is going 3 to be an issue, I would like to leave the 4 deposition open today, subject to the 5 production of any documents that I don't 6 have yet in the Eklund case. 7 MS. NAROTZKY: And this is Nicole 8 Narotzky on behalf of Medtronic. And a 9 couple of things, just in response, 10 Marlene, to your statement. 11 You know, we would be willing 12 certainly to meet and confer on that in 13 the future if need be but don't believe 14 that will be necessary, given the 15 productions that have been made and 16 agreed to. 17 The other thing that I would like 18 to add is that, you know, we have been 19 discussing the cross-notice stipulation 20 between the plaintiffs and defendants, 21 Medtronic defendants in the Eklund and 22 Brackin cases. And while we have 23 agreement on that from this morning that 24 has not yet been filed with the court, I
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1 MS. MARTINEZ: I just wanted to 2 say, this is Ileana Martinez from 3 Thompson Hine, that I am appearing on 4 behalf of Unomedical A/S in the Eklund 5 case only and only for defendant 6 Unomedical A/S, which is the only 7 defendant that has been serve in the 8 Eklund case. And based on the motions 9 and the court's order in the Brackin case 10 from yesterday, I will not be appearing 11 and am not appearing on behalf of any 12 defendant in the Brackin case, because 13 we, based on the motions to dismiss and 14 motion to quash and motion for protective 15 order, our position is that we have not 16 been -- Unomedical A/S and Unomedical 17 Devices has not been served at all, and 18 Unomedical A/S has not been properly and 19 timely served. 20 That's all. Thanks. 21 MS. GOLDENBERG: All right. I 22 will go next. 23 This is Marlene Goldenberg, and I 24 am here on behalf of the Eklund family.	1 would just note that the deposition is 2 being taken pursuant to the agreement 3 that we reached in that stipulation. 4 Any objections or comments on 5 that? 6 MR. HAVERTY: No. 7 MS. MARTINEZ: No. That's fine. 8 MR. HAVERTY: No. We agree. 9 MR. MERRELL: And then I have one 10 last thing, just so we don't have to 11 break up the flow. The deposition today 12 is being taken pursuant to the protective 13 orders entered in the Eklund and Brackin 14 cases. 15 - - - 16 (A discussion off the record 17 occurred.) 18 - - - 19 THE VIDEOGRAPHER: We are now on 20 the record. My name is David Kim. I'm a 21 videographer for Golkow Litigation 22 Services. Today's date is May 18, 2018, 23 and the time in Encino is 9:48 a.m. This 24 video deposition is taking place in

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<p>1 Encino, California, in the matter of 2 Brackin v. Medtronic, Inc., et al., and 3 is cross-noticed with other cases. 4 This is for the US District 5 Court, the Western District of Tennessee. 6 The deponent is Anatoly Aleksandrovich. 7 Counsel will be noted on the stenographic 8 record.</p> <p>9 The court reporter is Ann Marie 10 Mitchell and is in Philadelphia, and she 11 will now swear in the witness.</p> <p>12 - - -</p> <p>13 ANATOLY ALEKSANDROVICH, after 14 having been duly sworn, was examined and 15 testified as follows:</p> <p>16 - - -</p> <p>17 EXAMINATION</p> <p>18 - - -</p> <p>19 BY MR. HAVERTY:</p> <p>20 Q. Good morning, Mr. Aleksandrovich. 21 It's nice to see you again.</p> <p>22 A. Good morning. Likewise.</p> <p>23 Q. I'm sure you remember well about 24 three years ago when we were together for those</p>	<p>1 form, we may not whether the answer is yes or no. 2 So for the purposes of clarity and accuracy, 3 please give a yes, no or a narrative, descriptive 4 answer. All right?</p> <p>5 A. Understood.</p> <p>6 Q. Closely related to that is please 7 wait for me to finish asking my question before 8 you try to answer it. There are two important 9 reasons for that. One is that the court reporter 10 can't take down gestures like nods -- or excuse 11 me, can't take down both of us speaking at the 12 same time, but also that way you can 13 understand -- you can assure yourself that you 14 understood my question before you try to give an 15 answer. Okay?</p> <p>16 A. Okay.</p> <p>17 Q. And one other factor is playing 18 into this, is there's a little bit of a lag on 19 the audio, so hopefully that won't be too much of 20 an issue, but...</p> <p>21 Also, if at any time I ask you a 22 question that you don't have an exact answer to 23 or -- but you can provide us with a reasonable 24 approximation or estimation as distinct from a</p>
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<p>1 gueling depositions. Hopefully I'm not going to 2 try to re-plow any of that ground too much, but I 3 want to take your deposition today concerning 4 some developments that have happened as well 5 since that time, back in 2015 when we last met.</p> <p>6 Before we begin, let me give you 7 some instructions so that hopefully you 8 understand me, I'll understand you, and we'll get 9 through this process as quickly as we can.</p> <p>10 The first is that if at any time 11 I ask you a question that you don't understand or 12 it doesn't make sense to you, please tell me that 13 and I'll try to rephrase the question or 14 otherwise make it understandable. All right?</p> <p>15 A. Okay.</p> <p>16 Q. When you do give me an answer, 17 please make it a yes or a no or a narrative, 18 descriptive answer, because there is a court 19 reporter here taking down the testimony, and she 20 can't take down gestures like nods of the head 21 and shrugs of the shoulders. And even though you 22 may say uh-huh or uh-uh in response to a question 23 and we know sitting here today that you mean yes 24 or no, later on when this comes out in transcript</p>	<p>1 guess, it's okay to do that. Just please tell us 2 that you're approximating or estimating, so that 3 we understand whatever limitations or 4 qualifications there may be on your answer. All 5 right?</p> <p>6 A. Okay.</p> <p>7 Q. Very good.</p> <p>8 Let me just go back a little bit 9 with some of your background.</p> <p>10 What's your education and 11 training?</p> <p>12 A. Master's degree in manufacturing 13 engineering.</p> <p>14 Q. Where did you get that degree?</p> <p>15 A. In Tashkent State Technical 16 University.</p> <p>17 Q. In the former Soviet Union?</p> <p>18 A. Correct.</p> <p>19 Q. And where did you get your 20 undergraduate degree?</p> <p>21 A. Same -- there is no -- there is 22 no distinction. It was one program that 23 graduated with the master's.</p> <p>24 Q. Okay. They don't do it in the</p>

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<p>1 way we do it in the US where it's undergraduate 2 and then you go to graduate school?</p> <p>3 A. That is correct.</p> <p>4 Q. Okay. Great. By the way, let me 5 go back to something else before we get into your 6 background and your education and training.</p> <p>7 You've obviously given prior 8 deposition testimony on behalf of Medtronic. 9 Correct?</p> <p>10 A. I have.</p> <p>11 Q. Other than the deposition that 12 you gave in the Dennert and Kubicki matters back 13 in 2015, how many other depositions have you 14 given on behalf of Medtronic?</p> <p>15 A. One or two. I don't remember 16 exactly.</p> <p>17 Q. Do you recall when the last time 18 you gave deposition testimony was?</p> <p>19 A. No, I don't recall.</p> <p>20 Q. Okay. Do you know whether it was 21 within the last three years?</p> <p>22 A. It was before you took my 23 deposition last time.</p> <p>24 Q. Okay. So the deposition that I</p>	<p>1 When did you get that degree?</p> <p>2 A. In 1993.</p> <p>3 Q. And did you come to the US right 4 after that, or did you work in -- I guess by 1993 5 it was then -- the Soviet Union had broken up. 6 Right?</p> <p>7 A. It was about to break up, yes.</p> <p>8 Q. So did you remain in Russia or 9 whatever it was that you were in, or did you come 10 to the US?</p> <p>11 A. No. I came to the US in 12 September of 1993.</p> <p>13 Q. And how did you come to the US? 14 What was the arrangement for that? How did you 15 get a job?</p> <p>16 A. By -- by how, do you mean how did 17 I arrive physically or my alien status?</p> <p>18 Q. I'm talking about why did you 19 come to the US? Did you have a job here at that 20 point?</p> <p>21 A. No. The family decided to 22 immigrate.</p> <p>23 Q. Okay. So when you came in 24 September of 1993, did you -- were you able to</p>
<p style="text-align: center;">Page 19</p> <p>1 took of you in 2015 was the last time that you 2 testified on behalf of Medtronic?</p> <p>3 A. That is correct.</p> <p>4 Q. All right. Are you scheduled to 5 give any deposition testimony on behalf of 6 Medtronic other than this case or these cases at 7 this point?</p> <p>8 A. No, not at this point. No.</p> <p>9 Q. And I don't really remember from 10 your prior deposition, but the deposition 11 testimony that you gave prior to the 2015 12 depositions, did that have anything to do with 13 your role in running the CAPA involved with the 14 temporary vent block phenomenon?</p> <p>15 A. I don't remember exactly what the 16 previous deposition was on.</p> <p>17 Q. Okay. Did you give any 18 deposition testimony concerning the Lot 8 recall?</p> <p>19 A. No.</p> <p>20 Q. Were you involved at all in the 21 Lot 8 recall or the CAPA, anything like that?</p> <p>22 A. No, I was not.</p> <p>23 Q. So you told us that you have a 24 master's degree in manufacturing engineering.</p>	<p style="text-align: center;">Page 21</p> <p>1 get a job at that point?</p> <p>2 A. Soon after that.</p> <p>3 Q. And what did you do?</p> <p>4 A. Started as an inspector at a 5 small manufacturing company in Los Angeles.</p> <p>6 Q. What was -- what did they 7 manufacture?</p> <p>8 A. It was a job shop that 9 specializes in powder and metallurgy technology.</p> <p>10 Q. By the way, within the practice 11 of manufacturing engineering, did you have any 12 particular specialization?</p> <p>13 A. Yes. From an educational 14 standpoint, it was -- it was concentrated around 15 metal cutting technology.</p> <p>16 Q. Metal, I'm sorry, metal what?</p> <p>17 COURT REPORTER: Cutting.</p> <p>18 THE WITNESS: Metal cutting.</p> <p>19 BY MR. HAVERTY:</p> <p>20 Q. Is quality assurance part of 21 manufacturing engineering?</p> <p>22 A. It was not by my training.</p> <p>23 Q. Is it in your practice, though?</p> <p>24 A. In my practice, yes. Quality</p>

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<p style="text-align: right;">Page 22</p> <p>1 assurance is a part of anything and everything. 2 Q. So you were working at this metal 3 company. 4 Then what did you do after that? 5 A. Then after that, I went to a 6 company that manufactures turbo generators. 7 Q. Okay. And what did you do there? 8 A. A variety of things, progressing 9 from quality inspector to test engineer to 10 manufacturing engineer to project manager. 11 Q. For how long were you with that 12 firm? 13 A. Seven years, I believe. 14 Q. So this takes us into the early 15 2000s? 16 A. I was laid off from that company 17 in the late 2002. 18 Q. Okay. And what did you do after 19 that? 20 A. I went to another small company 21 that made -- worked on the power storage 22 technology. 23 Q. Okay. And what did you do there? 24 A. Manufacturing engineering.</p>	<p style="text-align: right;">Page 24</p> <p>1 A. After that I went to my first 2 medical device company -- 3 Q. What -- what -- 4 A. -- as an industrial engineer. 5 Q. And what company was that? 6 A. Advanced Bionics. 7 Q. Event Bionics? 8 A. Advanced Bionics. 9 Q. Advanced Bionics. Okay. 10 And you said you were a 11 industrial engineer. How did that differ from a 12 manufacturing engineer? 13 A. By -- in that particular 14 assignment, mostly by name. Instead of 15 concentrating on necessarily manufacturing 16 processes, my job was to -- to set up the 17 facility and auxiliary processes to ensure that 18 manufacturing happens in the most efficient way. 19 Q. It was more of an umbrella type 20 of an assignment rather than a more specific 21 setting up manufacturing processes? 22 A. That is correct, yes. 23 Q. And for how long did you have 24 that job?</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. And what did -- what did the role 2 of manufacturing engineer involve at that 3 company? 4 A. At that company was to set up a 5 manufacturing line for this product that the 6 company was working on and equip it with proper 7 equipment and also establish relationships with a 8 supplier for a long-term manufacturing plant. 9 Q. And for how long did you have 10 that job? 11 A. Just one year. 12 Q. And what did you do after that? 13 A. Then I went to the aerospace 14 company. 15 Q. Okay. And what did you do there? 16 A. I was there trained as a Six 17 Sigma Black Belt and primarily worked in the 18 manufacturing field as well. 19 Q. And for how long did you have 20 that job? 21 A. Let's see. 2003 -- three years. 22 Q. And that takes us up to 2006? 23 A. Correct. 24 Q. And what did you do after that?</p>	<p style="text-align: right;">Page 25</p> <p>1 A. Until 20 -- late 2008. 2 Q. And what did you do then? 3 A. Then Medtronic. 4 Q. Okay. 5 A. Starting in January 2009. 6 Q. And how did you get the job at 7 Medtronic in January of 2009? 8 A. I applied to an open position, 9 posted, I believe, on their website. 10 Q. What was the position? 11 A. I don't remember exactly. It was 12 a senior engineer. I don't remember exactly what 13 kind of engineer. 14 Q. Okay. And what were your -- what 15 were your job duties at that time? What lines 16 were you involved in? 17 A. I'm sorry. I didn't catch 18 your -- the last part of the question. 19 Q. Yeah. 20 A. What lines I was involved with? 21 Q. What products were you involved 22 with when you came to Medtronic? 23 A. Oh. It was a glucose sensor 24 manufacturing line.</p>

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<p style="text-align: right;">Page 26</p> <p>1 Q. And what was your job? 2 A. Like I said, senior engineer and 3 working on the manufacturing line, ramping up 4 production, setting up. 5 Q. That was a bad question. 6 What I meant was, could you give 7 me some sort of sense of what your job duties 8 were? 9 A. Okay. Validating processes, 10 procuring new equipment, installing it, 11 validating it and bringing it to production 12 state, working on setting up manufacturing lines 13 for newly-introduced products, working with 14 suppliers to ensure an uninterrupted flow of 15 parts. 16 Q. And let me just explore something 17 a little bit. 18 You talked about part of your job 19 is validating processes. 20 Do I understand that to mean that 21 basically when you're preparing a manufacturing 22 type of a system, you want to understand the 23 processes that go into that are -- actually work 24 to do what they're supposed to do, and that's</p>	<p style="text-align: right;">Page 28</p> <p>1 industry that you're talking about is something 2 that's part of the FDA requirements for medical 3 devices, is it not? 4 A. It is. 5 Q. And that's under the Quality 6 Systems Regulations. Correct? 7 A. Correct. 8 Q. That's Part 820 of the federal 9 rules? 10 A. I don't remember the number of 11 the regulation. 12 Q. Okay. But in any event, there's 13 a specific regulation that deals with, among 14 other things, validation of processes. Correct? 15 A. As far as I understand, yes. 16 Q. And we're going to get into this 17 in a little bit more detail in a bit, but also 18 part those regulations is a process of corrective 19 and preventative actions too. Correct? 20 A. I am not sure if this is the same 21 regulation as the validation. 22 Q. No. I'm not suggesting it is, 23 but I'm saying that within the quality systems 24 regulations, another thing in addition to</p>
<p style="text-align: right;">Page 27</p> <p>1 what you call validating them? 2 A. That's part of it. 3 Q. Okay. 4 A. It's a little more than that. 5 It's understanding the process and then 6 identifying the process and ensuring that the 7 process produces what's needed reliably and 8 repeatedly. 9 Q. Now, that type of validation 10 practice, is that a specialization within the 11 practice of manufacturing engineering? 12 A. No. I would not call it that, 13 no. Because manufacturing engineering covers 14 much more than just medical devices, and 15 validation is specific to medical devices. 16 Q. Oh, okay. So in other types of 17 manufacturing processes, you don't necessarily 18 have that type of a validation process? 19 A. That is correct. Either no 20 validation at all, it's done through a different 21 way, or not to the extent that it's done in the 22 medical device industry, so the answer is yes. 23 Q. Okay. And just so I understand, 24 this validation process in the medical device</p>	<p style="text-align: right;">Page 29</p> <p>1 validation processes is a requirement to have in 2 place corrective and preventative action 3 procedures. Correct? 4 A. That is correct. 5 Q. And those are FDA requirements. 6 Right? 7 A. Yes. 8 Q. Okay. So when you were -- when 9 you first joined Medtronic in 2009 and you were 10 working on the glucose monitor system, how long 11 did you do that position? 12 A. For about three years. 13 Q. And then what did you do? 14 A. And then I switched to 15 consumables. 16 Q. And what did the consumables 17 consist of? 18 A. Mostly infusion sets and 19 accessories to those infusion sets. 20 Q. Did it also include the 21 reservoirs? 22 A. Consumable -- consumables do 23 include reservoirs. I am not involved with 24 reservoirs.</p>

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<p style="text-align: right;">Page 30</p> <p>1 Q. Were you ever involved with 2 reservoirs?</p> <p>3 A. Not to any serious extent.</p> <p>4 Q. Okay. So what was your job when 5 you moved to consumables relating to the infusion 6 sets?</p> <p>7 A. Basically oversee the 8 manufacturing relationship with the supplier that 9 makes infusion sets. We don't make them 10 ourselves. And the entire manufacturing site of 11 the infusion set production, if you will.</p> <p>12 Q. And in 20 -- well, that was about 13 2012 that you moved over to consumables?</p> <p>14 A. Yes, that is correct.</p> <p>15 Q. Okay. And at the time when you 16 moved to consumables in 2012, who was the 17 manufacturer of the infusion sets?</p> <p>18 A. Unomedical.</p> <p>19 Q. And did you, as part of your job, 20 did you develop a relationship with Unomedical 21 about the manufacture of the infusion sets?</p> <p>22 A. So the -- the company-to-company 23 relationship were well established by then. I 24 developed my personal relationship with</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. And that was something that 2 Unomedical also manufactured and then assembled 3 with the infusion sets to -- or with the 4 catheters to create a complete infusion set. 5 Correct?</p> <p>6 A. That is correct.</p> <p>7 Q. And do you know for how long that 8 system had been in place, that Unomedical 9 manufactured both the cap, the connector cap, and 10 assembled the completed infusion set?</p> <p>11 A. No, I don't exactly.</p> <p>12 Q. Did you know that it had been 13 fairly long-standing at that point?</p> <p>14 MS. MARTINEZ: Object to the 15 form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. HAVERTY:</p> <p>18 Q. And when you first came over in 19 2012 to consumables, do you know whether there 20 were any material changes that were in place or 21 in progress at that time?</p> <p>22 A. No. To the best of my knowledge, 23 there was no such project at that time.</p> <p>24 Q. Was there -- were there any</p>
<p style="text-align: right;">Page 31</p> <p>1 Unomedical.</p> <p>2 Q. And what kinds of things -- were 3 there certain projects that you were working on 4 when you moved over to consumables?</p> <p>5 A. Yes. There is different ones.</p> <p>6 Q. Can you give me just some 7 sampling of some idea of some of the projects 8 that you were working on relating to the infusion 9 sets?</p> <p>10 A. It can be anything. It can be a 11 material change. It can be an equipment setup or 12 equipment expansion. It can be capacity increase 13 project. It can be packaging project or branding 14 project. All kind of things.</p> <p>15 Q. In 2012 when you first got 16 involved with the consumables, what kinds of 17 projects like you just described did you have 18 going at that time, if any?</p> <p>19 A. Probably all of the above, to 20 some extent, more -- more some than others.</p> <p>21 Q. The manufacture of the infusion 22 sets also included the manufacture of the 23 proprietary connector cap. Correct?</p> <p>24 A. That is correct.</p>	<p style="text-align: right;">Page 33</p> <p>1 changes in the manufacturing processes that were 2 contemplated or in progress at that time?</p> <p>3 A. No, not that I can remember.</p> <p>4 Q. So what would your day-to-day job 5 be in dealing with the consumables that were 6 manufactured by Unomedical?</p> <p>7 A. Mostly documentation change, 8 updates, review of validation documents provided 9 by Unomedical, things like that.</p> <p>10 Q. Okay. And what types of 11 validation documents was Unomedical providing to 12 you relating to the manufacture of the infusion 13 sets?</p> <p>14 A. Unomedical usually supplies a 15 summary report of validation activities.</p> <p>16 Q. And what do those validation 17 activities involve?</p> <p>18 A. They involve establishing the 19 manufacturing process and verification that the 20 process performs consistently within set 21 parameters.</p> <p>22 Q. And were they providing you these 23 summary reports on validation activities on a 24 regular basis?</p>

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<p style="text-align: right;">Page 34</p> <p>1 MS. MARTINEZ: Object to the 2 form. 3 THE WITNESS: It depends on 4 the -- on the project. 5 BY MR. HAVERTY: 6 Q. So there wasn't anything in place 7 that said on a monthly basis you will provide us 8 validation summaries? 9 A. That is correct. There is no 10 such schedule. 11 Q. So what would trigger a 12 validation report from Unomedical? Would it be 13 some change in the manufacturing process or 14 some -- some defect or something that was 15 discovered in the manufacturing process? 16 MS. MARTINEZ: Object to the 17 form. 18 THE WITNESS: A change in the 19 manufacturing process, an introduction of 20 a new piece of equipment, a move of a 21 piece of equipment from one place or 22 another, things like that. 23 BY MR. HAVERTY: 24 Q. And are you still in that same</p>	<p style="text-align: right;">Page 36</p> <p>1 by a company -- it is manufactured by a 2 company called SMC. 3 BY MR. HAVERTY: 4 Q. Are there any other products that 5 you oversee other than the belt clip and the 6 infusion sets? 7 A. Some accessories to the infusion 8 set, inserting mechanism, inserting devices. And 9 there is also a couple of new products that I got 10 involved with that -- that are not part of the 11 consumables product line, if you will. 12 Q. Let me go back a little bit, talk 13 to you about the connector cap for the infusion 14 sets. 15 The purpose of that connector cap 16 is to connect the catheter which delivers the 17 insulin into the body to the reservoir which 18 holds the insulin. Correct? 19 A. Correct. And to the pump. 20 Q. Right. Well, right. Because 21 then you connect it to the reservoir, the 22 reservoir goes in the pump, and the pump pumps 23 the insulin through the reservoir into the 24 catheter, into the body. Correct?</p>
<p style="text-align: right;">Page 35</p> <p>1 position today that you were when you first 2 joined in 2012? 3 A. Yes. 4 Q. Okay. And what's your title now? 5 A. Senior principal manufacturing 6 engineer. 7 Q. And do you still have 8 responsibility primarily for the infusion set 9 consumables? 10 A. Primarily, yes. 11 Q. Do you have responsibility for 12 any other products associated with the insulin 13 infusion pumps? 14 A. With the pumps, nothing other 15 than the belt clip. 16 Q. Oh, the belt clip. Okay. 17 Is the belt clip manufactured by 18 Medtronic too? 19 A. No, it is not. 20 Q. Okay. Who manufactures that? 21 THE WITNESS: Can I disclose it 22 here? 23 MR. MERRELL: Yes. 24 THE WITNESS: It is manufactured</p>	<p style="text-align: right;">Page 37</p> <p>1 A. Correct. 2 Q. And you are aware that that 3 connector cap is a proprietary, patented design 4 of Medtronic. Correct? 5 A. Correct. 6 Q. And were you aware that there was 7 a period of time when Medtronic actually did 8 manufacture that connector cap? 9 A. I am aware of that, yes. 10 Q. And how did you become aware of 11 that? 12 A. By learning the history of a 13 proprietary cap manufacturing. 14 Q. And was it your understanding 15 that part of the reason for the design of that 16 connector cap is because Medtronic was seeking to 17 make the pump waterproof? 18 A. No. That's not the main reason 19 for the proprietary cap. 20 Q. Okay. What is your understanding 21 of what the main reason for the proprietary cap 22 was? 23 A. Main reason is that Medtronic 24 pump connects only to Medtronic-designed infusion</p>

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<p>1 set.</p> <p>2 Q. So is it your understanding that</p> <p>3 no other types of infusion sets could be used</p> <p>4 with a Medtronic pump?</p> <p>5 A. Other than infusion sets equipped</p> <p>6 with a proprietary connector, yes.</p> <p>7 Q. So -- and so the reservoirs are</p> <p>8 designed specifically for that connector cap as</p> <p>9 well?</p> <p>10 A. Correct.</p> <p>11 Q. Can those reservoirs be used with</p> <p>12 a standard Luer Lock connector?</p> <p>13 A. So we're going to have to be a</p> <p>14 little bit more clear on this.</p> <p>15 We do or we used to manufacture a</p> <p>16 reservoir that will work with the Luer Lock</p> <p>17 connector. And then there are reservoirs</p> <p>18 designed and manufactured to work only with a</p> <p>19 proprietary connector.</p> <p>20 Q. So the reservoirs that are</p> <p>21 designed for connection with the proprietary</p> <p>22 connector will not work with a Luer Lock</p> <p>23 connector?</p> <p>24 A. That is correct.</p>	<p>1 Q. You don't remember any CAPAs that</p> <p>2 you might have been involved in other than the</p> <p>3 CAPA involving the temporary vent block. Right?</p> <p>4 A. Correct.</p> <p>5 Q. And you were aware, though, when</p> <p>6 you came on to the consumables about the Lot 8</p> <p>7 recall. Correct?</p> <p>8 A. That is correct.</p> <p>9 Q. And were you aware of the Lot 8</p> <p>10 recall when it first happened? You were working</p> <p>11 at Medtronic at that time in 2009. Right?</p> <p>12 A. Yes.</p> <p>13 Q. Okay.</p> <p>14 A. But I was not aware right as it</p> <p>15 happened, because I was not involved with that</p> <p>16 product line at the point -- at the time.</p> <p>17 Q. Okay. Because you were doing the</p> <p>18 glucose monitors. Right?</p> <p>19 A. That's correct, yes.</p> <p>20 Q. But at some point you became</p> <p>21 familiar with the details of the Lot 8 recall?</p> <p>22 A. Yes.</p> <p>23 Q. Was that before or after you</p> <p>24 headed up the CAPA relating to the vent block?</p>
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<p>1 Q. Are there reservoirs out there</p> <p>2 that are not Medtronic reservoirs that would</p> <p>3 still work in a Medtronic pump?</p> <p>4 A. No, not to my knowledge.</p> <p>5 Q. So again, are the reservoirs that</p> <p>6 are designed to connect only to the proprietary</p> <p>7 cap, are they the only reservoirs that will work</p> <p>8 in a Medtronic 5 series pump?</p> <p>9 A. Yes. To the best of my</p> <p>10 knowledge, yes.</p> <p>11 Q. And we're going to get into this</p> <p>12 in a little bit more detail shortly, but you led</p> <p>13 the corrective and preventative action -- and</p> <p>14 we're going to call them CAPAs from now on for</p> <p>15 the benefit of the court reporter -- involve --</p> <p>16 dealing with the temporary vent block phenomenon.</p> <p>17 Correct?</p> <p>18 A. Correct.</p> <p>19 Q. Other than that CAPA, have you</p> <p>20 ever been involved with any other CAPAs at</p> <p>21 Medtronic?</p> <p>22 A. I don't remember. Definitely not</p> <p>23 as a lead. As a team member I may have, but I</p> <p>24 don't remember.</p>	<p>1 A. Before.</p> <p>2 Q. And do you recall how you became</p> <p>3 aware of the details of the Lot 8 recall?</p> <p>4 A. Yeah. By a company-wide</p> <p>5 announcement.</p> <p>6 Q. And what was your understanding</p> <p>7 of what the problem was that led to the Lot 8</p> <p>8 recall?</p> <p>9 A. It was a manufacturing process</p> <p>10 issue.</p> <p>11 Q. And what did that manufacturing</p> <p>12 process issue do that caused the recall, that led</p> <p>13 to the recall?</p> <p>14 A. So the manufacturing process</p> <p>15 employed at that time included deposition of some</p> <p>16 silicone oil onto the inner surface of the P-cap</p> <p>17 to prevent -- to -- to make the connection easier</p> <p>18 and to prevent the sounds the two materials were</p> <p>19 make -- were to make. And that eventually led to</p> <p>20 some of that silicone oil being deposited onto</p> <p>21 the membrane and rendering it gas impermeable.</p> <p>22 Q. So that -- and just -- we're</p> <p>23 going to talk about this in more detail. But</p> <p>24 that's exactly the same failure mechanism as was</p>

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<p>1 discovered in the temporary vent block 2 phenomenon. Correct? 3 MR. MERRELL: Objection to form. 4 THE WITNESS: No, not the 5 mechanism. Failure mode. The failure 6 itself but not the mechanism. 7 BY MR. HAVERTY: 8 Q. I stand corrected. Yes. You're 9 right. 10 The failure mode was the same, 11 and that is blocking of the vents that prevents 12 equalization of the pressure. Right? 13 A. Potentially, yes. 14 Q. Okay. So back at the time of the 15 Lot 8 recall, Medtronic was aware of a problem 16 with insulin delivery if the vents in the 17 proprietary cap got blocked. Right? 18 MR. MERRELL: Objection to form. 19 THE WITNESS: Yes. After 20 investigation of Lot 8, yes. 21 BY MR. HAVERTY: 22 Q. Let me shift gears a little bit 23 and talk about CAPAs. We were touching on this a 24 little bit.</p>	<p>1 talk about a little bit. 2 What is it that would trigger a 3 CAPA ultimately? 4 A. I can't answer that question 5 directly. First of all, I'm not in the quality 6 systems -- I mean, I'm trained on all the quality 7 systems, but there are multiple steps leading to 8 a CAPA, and I cannot tell you just one way or the 9 other what exactly leads to a CAPA. It's a 10 complex of -- of activities involving a lot of 11 people from different functions. 12 Q. But again, that's kind of a -- 13 there's a multistep process that leads to a 14 decision about whether to open a CAPA or not open 15 a CAPA. Correct? 16 A. Correct. 17 Q. And part of that decision-making 18 is an assessment of the risk to patient safety. 19 Correct? 20 A. That is correct. 21 Q. And again, when we talk about 22 it's a corrective and preventative action, the 23 corrective part of it means that you -- you're 24 correcting a problem in the near term. Correct?</p>
<p>1 CAPAs stand for corrective and 2 preventative actions. Correct? 3 A. Correct. 4 Q. And would you agree with me that 5 a CAPA is a high-level risk mitigation process? 6 A. It's not just the risk mitigation 7 process, but in general, yes. 8 Q. It's not something that you enter 9 into just because you find some type of a small 10 deviation from something. It's usually where 11 there's a hazard that's been identified, and that 12 hazard poses a risk to patients' health and 13 safety. Right? 14 MR. MERRELL: Objection to form. 15 MS. MARTINEZ: Same objection. 16 THE WITNESS: There is a -- there 17 is a multistep process -- we didn't call 18 it a system -- at Medtronic that leads to 19 a CAPA. And not every failure identified 20 or not every deviation identified results 21 in a CAPA. There are many different ways 22 to address an issue identified. 23 BY MR. HAVERTY: 24 Q. Right. And that's what I want to</p>	<p>1 A. Not necessarily correct. You can 2 correct it in the near term or in the long term. 3 It depends on the corrective action -- 4 Q. Right. 5 A. -- identified. 6 Q. Right. What I'm saying is, is 7 that initially you want to correct whatever the 8 perceived problem is and understand what the root 9 cause is and then take preventative action to 10 prevent that problem from arising in the future. 11 Right? 12 MR. MERRELL: Object to the form. 13 THE WITNESS: That's -- that's 14 high level. But again, it's very, very 15 specific to an issue at hand. 16 BY MR. HAVERTY: 17 Q. Right. I'm just trying to 18 understand the concept of the process. The 19 process -- that's why it's called corrective and 20 preventative. So first things first is you 21 correct the perceived problem, and then you 22 figure out whether there's anything necessary to 23 be done to prevent that problem from arising 24 again in the future. Right?</p>

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<p>1 MR. MERRELL: Object to the form. 2 THE WITNESS: Correct. 3 BY MR. HAVERTY: 4 Q. So the corrective action might be 5 something like a field notification or a recall. 6 Right? 7 A. Depending on the situation, might 8 be. 9 Q. Right. And a preventative action 10 might be perhaps a redesign of the product to 11 mitigate or eliminate whatever hazard is 12 perceived. Correct? 13 A. Might be. Again, depending on 14 the situation. Correct. 15 Q. Okay. And again, we talked about 16 this a little while ago. This is something that 17 is required by the FDA to be in place. Correct? 18 A. Yes, it is. 19 Q. So -- and are you required to 20 report to the FDA when CAPAs are opened and what 21 the dispositions of those CAPAs are? 22 A. I wouldn't be able to -- I don't 23 know exactly how reporting happens and what 24 drives reporting.</p>	<p>1 A. Correct. 2 Q. And then the next most preferable 3 is if you can't design the hazard out, then you 4 guard against it. Correct? 5 A. Correct. 6 Q. And both of those risk mitigation 7 techniques are designed to take out the human 8 factor in risk mitigation. Correct? 9 A. As much as possible. 10 Q. And then the third risk 11 mitigation technique and the least desirable of 12 the three is if you can't design the hazard out 13 and you can't guard against it, then you warn 14 about it. Right? 15 MR. MERRELL: Object to form. 16 THE WITNESS: Yes. 17 BY MR. HAVERTY: 18 Q. And the problem with warnings is 19 that it still involves the human factor. 20 Correct? 21 MR. MERRELL: Objection to form. 22 THE WITNESS: Yes. 23 BY MR. HAVERTY: 24 Q. And when you open up these CAPAs</p>
<p>1 Q. Okay. And let's talk a little 2 bit about -- we touched on it a little bit, but 3 risk mitigation as CAPA is one part of that 4 process. 5 You would agree with me that 6 there is a hierarchy of risk mitigation -- risk 7 mitigation processes, the first being if you 8 detect a hazard, you try to design that hazard 9 out. Right? 10 MR. MERRELL: Object to form. 11 THE WITNESS: I'm not very clear 12 on the question. 13 BY MR. HAVERTY: 14 Q. Okay. It was a terrible 15 question, and I apologize. 16 You're aware that there's a 17 hierarchy of risk management techniques? 18 A. Correct. 19 Q. Or risk mitigation techniques. 20 Correct? 21 A. Yes. 22 Q. And the hierarchy -- the 23 hierarchy, the most desirable technique for risk 24 mitigation is to design out a hazard. Correct?</p>	<p>1 where you've identified a particular hazard or 2 some issue, is that part of the CAPA process is 3 to go down the list of the hierarchy to determine 4 whether or not you can design the problem out, 5 whether you can guard against it or whether 6 you're left with having to warn about it? 7 A. So the process you're referring 8 to is not a part of my responsibility at 9 Medtronic, and I'm usually not involved in that 10 early stage of the CAPA, so I can't really answer 11 exactly how it happens and how it's supposed to 12 happen. 13 Q. Right. But part of the CAPA 14 process is, well, we'll just do it, is the first 15 thing you want to do is you identify the root 16 cause of the problem. Correct? 17 A. Once you go into investigation 18 phase of the CAPA, yes. 19 Q. Okay. And let's go back and talk 20 specifically about the CAPA that was opened 21 relating to the vent block in 2013. 22 That CAPA arose out of 23 complaints, and then there was a situation 24 analysis done and a health hazard evaluation was</p>

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<p>1 done and a risk assessment. Correct?</p> <p>2 A. Correct.</p> <p>3 Q. And based upon those initial</p> <p>4 stages of the investigation, there was a</p> <p>5 determination that was made to open up a CAPA.</p> <p>6 Correct?</p> <p>7 A. Correct.</p> <p>8 Q. And you would agree with me --</p> <p>9 I'm going to shift gears a little bit -- but that</p> <p>10 in the spring of 2013, Medtronic uncovered a</p> <p>11 hazard that was associated with the design of the</p> <p>12 proprietary connector cap. Correct?</p> <p>13 MR. MERRELL: Objection to form.</p> <p>14 MS. MARTINEZ: Objection.</p> <p>15 THE WITNESS: No, no. Incorrect.</p> <p>16 BY MR. HAVERTY:</p> <p>17 Q. What was incorrect about that?</p> <p>18 Did Medtronic identify a hazard?</p> <p>19 A. The hazard was identified, that</p> <p>20 is correct, but it was not connected or due to</p> <p>21 design issues.</p> <p>22 Q. Well, it was due to a material in</p> <p>23 the underside of the connector cap that could</p> <p>24 become gas impermeable if it got wet. Correct?</p>	<p>1 was finally uncovered in 2013. Right?</p> <p>2 MR. MERRELL: Objection to form.</p> <p>3 THE WITNESS: Again, I wouldn't</p> <p>4 call it a design flaw, but yes, it was an</p> <p>5 issue.</p> <p>6 BY MR. HAVERTY:</p> <p>7 Q. Okay. And in fact, when a</p> <p>8 determination was made to redesign that material</p> <p>9 to mitigate the hazard. Correct?</p> <p>10 A. Ultimately, yes.</p> <p>11 Q. Okay. So the initial thought</p> <p>12 process was we've identified a hazard, and were</p> <p>13 you tasked with the job of determining whether or</p> <p>14 not in the hierarchy of risk mitigation, that</p> <p>15 hazard could be designed out?</p> <p>16 A. I was tasked eventually with --</p> <p>17 yes. With -- to lead the team to figure that</p> <p>18 out.</p> <p>19 Q. Okay. And that's because that</p> <p>20 was Medtronic's preferred method of risk</p> <p>21 mitigation?</p> <p>22 MR. MERRELL: Objection to form.</p> <p>23 THE WITNESS: There is no</p> <p>24 preferred method to risk mitigation. It</p>
<p>1 MR. MERRELL: Objection to form.</p> <p>2 THE WITNESS: That is correct.</p> <p>3 BY MR. HAVERTY:</p> <p>4 Q. And that was -- that was the</p> <p>5 original design of the -- that membrane material</p> <p>6 in the P-cap, that it would -- it was a two-layer</p> <p>7 membrane. Correct?</p> <p>8 A. It was the original design, but</p> <p>9 the unit was not designed or not intended to be</p> <p>10 used in the environment where any type of liquid</p> <p>11 would be present on that surface.</p> <p>12 Q. Right. But the fact is, is that</p> <p>13 you identified a hazard that was associated with</p> <p>14 the design. The design of that connect -- the</p> <p>15 membrane material in that P-cap could give rise</p> <p>16 to a hazard if it got wet on the inside.</p> <p>17 Correct?</p> <p>18 A. Correct.</p> <p>19 MR. MERRELL: Objection to form.</p> <p>20 THE WITNESS: As a consequence to</p> <p>21 not following instructions.</p> <p>22 BY MR. HAVERTY:</p> <p>23 Q. Right. But the fact is, is that</p> <p>24 there was a design flaw in it that, you know, it</p>	<p>1 can consist of a number of different</p> <p>2 things.</p> <p>3 BY MR. HAVERTY:</p> <p>4 Q. Well, again, we were talking a</p> <p>5 little bit earlier about it is if you identify a</p> <p>6 hazard, the most preferable course of action is</p> <p>7 to see if you can design that hazard out. Right?</p> <p>8 A. True. But that's not Medtronic</p> <p>9 specific.</p> <p>10 Q. Right. But am I correct that</p> <p>11 Medtronic made a commitment to the FDA that they</p> <p>12 would look to see if they could design</p> <p>13 alternative membrane material to mitigate that</p> <p>14 hazard?</p> <p>15 A. Okay. I can't speak to the</p> <p>16 commitments made to the FDA, and I'm not very</p> <p>17 familiar with that correspondence between</p> <p>18 Medtronic and FDA; but the project team</p> <p>19 determined that that -- to redesign or to</p> <p>20 introduce a new material would be the ultimate</p> <p>21 solution to the problem.</p> <p>22 MR. HAVERTY: Cliff, do you want</p> <p>23 to take a real -- like a two-minute break</p> <p>24 right here, because --</p>

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1 THE WITNESS: That would actually 2 be nice. 3 MR. HAVERTY: Would that be 4 perfect? 5 MR. MERRELL: Sure. 6 MR. HAVERTY: Okay. 7 MR. MERRELL: Yeah, that's fine. 8 THE VIDEOGRAPHER: We are now 9 going -- 10 MR. HAVERTY: I'm sorry. Go 11 ahead. 12 THE VIDEOGRAPHER: We are now 13 going off the record, and the time is 14 10:29 a.m. 15 - - - 16 (A recess was taken from 10:29 17 a.m. to 10:39 a.m.) 18 - - - 19 THE VIDEOGRAPHER: We are now 20 going back on the record, and the time is 21 10:39 a.m. 22 BY MR. HAVERTY: 23 Q. Mr. Aleksandrovich, the hazard 24 that we were talking about involving the	1 a placeholder for the pumpenfehler video. 2 MR. MERRELL: Do you want us to 3 have it out or anything or -- or just 4 give it to -- 5 MR. HAVERTY: No. I just want to 6 let you know that -- 7 MR. MERRELL: Okay. 8 MR. HAVERTY: Just so you can 9 identify it. 10 MR. MERRELL: Understood. 11 MR. HAVERTY: This is Exhibit 12 6 -- not this one. No, the other one. 13 - - - 14 (Deposition Exhibit No. AA-6, 15 Video file, was marked for 16 identification.) 17 - - - 18 MR. HAVERTY: So anyway, Cliff, 19 that is just a placeholder for the video, 20 Exhibit 6. 21 MR. MERRELL: Understood. 22 MR. HAVERTY: All right. So 23 we're going to play this. 24 BY MR. HAVERTY:
1 temporary vent block, that was first uncovered 2 arising out of a complaint from a customer in 3 September of 2012 about an anomaly during the 4 priming process of the pump. Correct? 5 A. To the best of my knowledge, 6 yeah. I joined the project team much later than 7 that. 8 Q. Right. But your understanding 9 was that that's what -- that's what set 10 everything in motion initially. Correct? 11 A. Yes. 12 Q. And your understanding is that 13 they provided a video of this phenomenon as well. 14 Correct? 15 A. There was a video, yes, correct. 16 Q. And you've seen that video. 17 Correct? 18 A. Correct. 19 Q. This is -- I believe it's 20 Exhibit 6, but let me check here real quickly. 21 I just want to play that video. 22 I believe it's Exhibit 6. There's a -- there's a 23 placeholder -- yeah. It's Exhibit 6. 24 In the binder there, Cliff. It's	1 Q. Okay. Can you see that? Can you 2 see the video there of the pump? 3 A. Yes. 4 Q. Okay. Great. We're going to 5 play it. So if you can take a look at this, 6 Mr. Aleksandrovich. 7 - - - 8 (Video played.) 9 - - - 10 BY MR. HAVERTY: 11 Q. Mr. Aleksandrovich, you recognize 12 that video as the video from Germany that was -- 13 started this whole process, the investigation? 14 A. I do. 15 Q. Okay. And you've seen that 16 before. Correct? 17 A. Correct. 18 Q. And I probably will need to play 19 it for you again, but I just want to ask you a 20 couple of questions. 21 Would you agree with me that what 22 was seen on that video is that the stopper in the 23 reservoir began moving before the slide screw 24 engaged the reservoir stopper?
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1 A. That is correct. 2 Q. And would you also agree with me 3 that the slide screw seated itself even while the 4 reservoir was moving -- reservoir stopper was 5 moving on its own? 6 A. I don't think I've seen the 7 seating mechanism. I think the priming action 8 was stopped before it seated itself. 9 Q. Okay. Let's go back and play 10 that then again. Let's see. 11 A. Okay. 12 - - - 13 (Video played.) 14 - - - 15 BY MR. HAVERTY: 16 Q. So you can see that it's 17 advancing there. Correct? 18 A. Yes, correct. 19 Q. And right about there the 20 reservoir stopper starts to move. 21 A. Right? 22 Q. Do you see it? 23 And then you hear the three 24 beeps.	1 A. Yes, but it doesn't mean that 2 they stop pushing it. 3 Q. Well, that's what I'm saying, is 4 that the person's finger is still on the "act" 5 button, but the slide screw has stopped on its 6 own. Correct? 7 Do you want to play it again? 8 A. Yes. Because I don't agree with 9 what you're saying. 10 MR. HAVERTY: Back up a little 11 bit. 12 THE WITNESS: Just a couple of 13 seconds, not the whole thing. 14 - - - 15 (Video playing.) 16 - - - 17 BY MR. HAVERTY: 18 Q. Yeah. And you'll hear the three 19 audio beeps, and you'll see that the finger is 20 still on it, and yet the slide screw stops. Right? 21 A. Yep, okay. 22 Q. So is it your testimony that you 23 do not believe that the slide screw there has
1 Isn't that the seated -- the 2 slide screw has seated at that point. Correct? 3 A. I'm not familiar with the -- with 4 the audible signals that the pump makes when it's 5 seated, but it's clearly not seated. 6 Q. Well, no. My question is a 7 little bit different. 8 My question is, is that the slide 9 screw advances until it detects a certain 10 pressure, and then it detects itself as having 11 been seated. Correct? 12 A. Again, I'm not -- I'm not -- to 13 my shame, actually, I'm not that familiar with 14 the pump operate -- operating, but visually right 15 now what I'm seeing in the picture on the screen, 16 the slide is not engaged with the plunger. 17 Q. Right. But that's different than 18 specifically what seating is. Right? 19 A. No, I don't think so. Seating 20 means that they're connected to the point where 21 therapy can start. 22 Q. Right. But that's -- let me ask 23 this question: You see that the person's finger 24 is still on the "act" button. Correct?	1 detected that it was seated? 2 A. Again, I can't answer that 3 question. I'm not that familiar with the pump 4 operation. 5 - - - 6 (A discussion off the record 7 occurred.) 8 - - - 9 BY MR. HAVERTY: 10 Q. Now, you would agree with me that 11 there was also -- in addition to this video, 12 there were also reports from -- also from 13 Germany, and they had returned infusion sets for 14 examination. Correct? 15 MR. MERRELL: Objection to form. 16 THE WITNESS: I don't remember 17 details to that extent. 18 BY MR. HAVERTY: 19 Q. Okay. 20 A. Again, I joined the team later 21 than -- later -- at a later date. 22 Q. Right. Okay. So if you could 23 look at Exhibit 2. 24 - - -

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<p>1 (Deposition Exhibit No. AA-2, 2 CAPA Full Detail Report with five Family 3 Tree Levels - PDF, Bates stamped 4 MDT-BRACP-028983 through 5 MDT-BRACP-029065, was marked for 6 identification.) 7 - - - 8 MR. MERRELL: We have a slight 9 binder malfunction. Sorry. It's bent 10 now. 11 MR. HAVERTY: I put a lot of care 12 into that, Cliff. 13 MR. MERRELL: I'm sure you did, 14 but unfortunately UPS may not have put 15 the same care into it. Oh, it's a 16 serious malfunction. 17 It's okay. Let's pull it out. 18 We'll just have to pull it out. 19 That's -- which maybe is easier anyway. 20 BY MR. HAVERTY: 21 Q. And let me just ask you a couple 22 of -- are you okay? -- foundational questions, 23 Mr. Aleksandrovich. This Exhibit 2 is captioned 24 as a "CAPA Full Detail Report with five Family</p>	<p>1 A. Correct. 2 Q. And indeed, it says up there at 3 the top, "PR State: Closed - Done." And 4 underneath it says, "Since: 10-November-2016." 5 Correct? 6 A. Yes, correct. 7 Q. So that's when this CAPA was 8 closed out. Correct? 9 A. Correct. 10 Q. So it was opened for about 11 three-and-a-half years. Right? 12 A. Yes. 13 Q. Okay. And if you look down under 14 the "Description" -- and I assume this CAPA 15 document went through multiple iterations over 16 the course of three-and-a-half years. Correct? 17 A. Correct. 18 Q. But this one -- this one we're 19 looking at, this last one should contain all the 20 pertinent information about the CAPA over the 21 course of that three-and-a-half years. Right? 22 A. Right. It should. 23 Q. So this would be a good source 24 for the history and the chronology of events that</p>
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<p>1 Tree Levels." 2 Do you see that? 3 A. Yes. 4 Q. Okay. And underneath that, it 5 has a -- well, the PR number is 158416. That's 6 the CAPA ID number? 7 A. Correct, yes. 8 Q. Okay. And this was created on 9 April 30th of 2013. Correct? 10 A. Looks like it, yes. 11 Q. And this was the CAPA that you -- 12 you led. Correct? 13 A. Yes, it is. 14 Q. And it's titled "QIR#13-006 P-cap 15 Infusion Sets Prime Fill Anomaly." Correct? 16 A. Correct. 17 Q. And what this report that you're 18 looking at is -- as Exhibit 2 is actually the 19 CAPA closing document, is it not? 20 A. It's the entire report on the 21 CAPA, not necessarily closing. This is the last 22 version of that report, yes. 23 Q. Right. Which means that the CAPA 24 was closed at that point. Correct?</p>	<p>1 took place during the course of this CAPA 2 investigation. Right? 3 A. Yes. Correct. 4 Q. And the information that's in 5 here, is this information that you would have put 6 into the CAPA, or did you derive information from 7 other sources as well? 8 A. Both. And the information was -- 9 that was placed -- at least the initial 10 information was placed in here, like I said, 11 before I picked it up -- 12 Q. Okay. So the part -- 13 A. -- as a project lead, yeah. 14 Q. The part under the "Description," 15 who would have put that in there? 16 A. I can't answer that question. 17 Whoever opened this record. 18 Q. Who other than you would have had 19 access to the CAPA, the document? 20 A. Any number of people. CAPA 21 administrators and quality engineers and -- it's 22 not something that only person gets record -- 23 access to. 24 Q. So under the "Description," it</p>

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<p>1 says that "Medtronic MiniMed received a complaint 2 call, Service Notification (SVN) 303925131, on 3 September 18, 2012 by a customer describing an 4 unusual behavior of the Paradigm insulin delivery 5 system during manual prime/fill cycle."</p> <p>6 Do you see that?</p> <p>7 A. Yes, I do.</p> <p>8 Q. Okay. And was -- to your 9 knowledge, is that complaint the one that was 10 associated with the video that we just played?</p> <p>11 A. I cannot answer that question. I 12 don't know.</p> <p>13 Q. Okay. But there was some 14 complaint that triggered it, and it was 15 associated with the videotape, a video like that. 16 Right?</p> <p>17 A. Yes, correct.</p> <p>18 Q. It goes on, "According to the 19 customer, after filling the reservoir and 20 connecting it to the infusion set," and it 21 identifies that as MMT-8 66 Sure-T, Lot #5002095, 22 "the reservoir was loaded into a model MMT-754 23 insulin pump and a manual prime sequence was 24 started. The customer noted that the insulin</p>	<p>1 fact it wasn't until -- I believe it was Mark 2 Curtis actually noticed some diluent fluid, the 3 fluid that's used in place of insulin for testing 4 purposes, on the inside of the connector cap?</p> <p>5 A. In one of his tests, yes. But I 6 don't think they were necessarily the infusion 7 sets returned from the customer.</p> <p>8 Q. No. You're correct. They 9 weren't. But it was sort of an incidental 10 finding by him that he made after he realized 11 that he probably hadn't filled the reservoir 12 correctly?</p> <p>13 A. Correct. Yes. I remember that.</p> <p>14 Q. Right. And that the insulin 15 spilled out from the -- or the diluent, the green 16 fluid, spilled out from the vial when he 17 disconnected the reservoir while it was 18 underneath the insulin vial. Right?</p> <p>19 A. Yes. While it was still 20 connected to a pressurized insulin vial, yes --</p> <p>21 Q. So --</p> <p>22 A. -- or diluent vial.</p> <p>23 Q. So he hypothesized that the 24 insulin could be blocking the vents if it got</p>
<p>1 started flowing through the cannula of the 2 infusion set before the plunger of the pump 3 physically engaged the stopper of the reservoir 4 and that the insulin continued flowing after the 5 manual prime cycle was aborted by the customer."</p> <p>6 Do you see that?</p> <p>7 A. I do.</p> <p>8 Q. All right. And that's consistent 9 with what we observed in that video, that the 10 stopper of the reservoir, the plunger, was moving 11 ahead of the slide screw. Correct?</p> <p>12 A. Correct.</p> <p>13 Q. And is it your understanding that 14 there were some infusion sets that were returned 15 for testing that were associated with this 16 complaint?</p> <p>17 A. Again, yes, I think so. I don't 18 remember exactly.</p> <p>19 Q. Do you remember that there was 20 some testing that was done on those returned 21 infusion sets and they couldn't reproduce the 22 phenomenon?</p> <p>23 A. Yes, I do.</p> <p>24 Q. Okay. And do you recall that in</p>	<p>1 spilled on the inside of the connector cap. 2 Right?</p> <p>3 A. So if it got spilled on the top 4 of the reservoir --</p> <p>5 Q. Right.</p> <p>6 A. -- not removed and after that 7 reservoir would be connected to the cap, then 8 that insulin or fluid would be transferred into 9 the P-cap membrane.</p> <p>10 Q. And then he actually went and 11 made a video demonstrating that phenomenon. 12 Correct?</p> <p>13 A. That's correct.</p> <p>14 Q. And then that triggered a review 15 of the returned insulin infusion sets where they 16 developed a test to determine the presence of 17 residual insulin on the inside of the caps. 18 Correct?</p> <p>19 A. Yes.</p> <p>20 Q. And when they went back and they 21 tested the returned infusion sets that were 22 associated with this phenomenon, this complaint, 23 they found in fact residual insulin on the inside 24 of the connector cap. Correct?</p>

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<p style="text-align: right;">Page 70</p> <p>1 A. I don't remember exactly the 2 findings, but yes. The test was developed, and 3 Mark did some trials, Mark Curtis did some 4 trials. I don't remember the details as to which 5 ones he tested and what were the outcomes.</p> <p>6 Q. Okay. But do you recall that at 7 some point there were tests for residual insulin 8 that came back positive, that they found residual 9 insulin on the inside of the caps?</p> <p>10 A. Yes.</p> <p>11 Q. And then -- let's show -- this is 12 Exhibit --</p> <p>13 Do you recall that there was a 14 video that was made to educate people within 15 Medtronic about this phenomenon back in the 16 spring of 2013? Do you recall that?</p> <p>17 A. No, I don't.</p> <p>18 Q. If you could look at -- if just 19 look at the photograph of Exhibit 14.</p> <p>20 - - -</p> <p>21 (Deposition Exhibit No. AA-14, 22 Video, was marked for identification.)</p> <p>23 - - -</p> <p>24 BY MR. HAVERTY:</p>	<p style="text-align: right;">Page 72</p> <p>1 to a situation analysis concerning the 2 phenomenon?</p> <p>3 A. Yeah. Again, I'm not exactly 4 sure of the sequence of events, but they were 5 able to replicate the phenomenon, yes.</p> <p>6 Q. And can you tell us what a 7 situation analysis is?</p> <p>8 A. A situation analysis, to my 9 knowledge, is a set of activities that -- you can 10 call it initial -- initial attempt to a root 11 cause analysis and also a risk assessment when 12 there is something -- something out of the 13 ordinary happens with the -- with a product, 14 whether it's done by -- through a complaint from 15 a customer or something found internally, it's 16 basically initial risk assessment and initial 17 data assessment, if you will.</p> <p>18 Q. And that's sort of the first step 19 in the process of an investigation, where you've 20 got a hazard that's potentially identified. 21 Correct?</p> <p>22 A. Correct.</p> <p>23 Q. I guess that's why it's called a 24 situational analysis. You want to understand</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. Yeah, you see it on the screen. 2 Do you recall seeing this video, 3 Mr. Aleksandrovich?</p> <p>4 A. Not at this point. If you show 5 me the video, maybe it will refresh.</p> <p>6 Q. I'm going to. So we'll play this 7 right now. This is Exhibit 14.</p> <p>8 - - -</p> <p>9 (Video played.)</p> <p>10 - - -</p> <p>11 BY MR. HAVERTY:</p> <p>12 Q. Yes. So have you ever seen that 13 video before?</p> <p>14 A. Never seen this video. It's a 15 great video, and I'm ashamed that I've never seen 16 it.</p> <p>17 Q. I was going to ask you, is what's 18 depicted on that video consistent with your 19 understanding of how the vent blockage could 20 occur and what the consequences of that would be?</p> <p>21 A. Yes, it is.</p> <p>22 Q. All right. And you were aware 23 that based upon that testing and -- they were 24 able to replicate the phenomenon, that that led</p>	<p style="text-align: right;">Page 73</p> <p>1 what it is that you're looking at initially to 2 determine what steps you might want to take to 3 investigate further. Right?</p> <p>4 A. That's right.</p> <p>5 Q. And depending upon what the 6 initial assessment of the situation analysis is, 7 that could lead to a health hazard evaluation. 8 Correct?</p> <p>9 A. It can. Like I said, it can lead 10 to any number of things.</p> <p>11 Q. Okay. Other than a health hazard 12 evaluation, what would a situation analysis -- or 13 strike that.</p> <p>14 Is a health hazard evaluation an 15 escalation from a situation analysis?</p> <p>16 A. I can't answer. I'm not super 17 familiar with that procedure, again, which -- 18 what is an escalation, what is the -- what leads 19 into that and what is the consequence of what.</p> <p>20 Q. But you would agree with me, 21 though, that opening a CAPA is sort of the 22 ultimate escalation from these types of 23 complaints. Correct?</p> <p>24 A. That I agree with.</p>

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<p>1 Q. And as a matter of fact, at 2 Medtronic diabetes, is there a CAPA board? 3 A. There is a CAPA board. 4 Q. And the purpose of the CAPA board 5 is to make decisions as to whether a CAPA is 6 required, given a particular situation. Right? 7 A. Correct. 8 Q. So you would have these various 9 escalations leading to a decision about whether 10 or not to submit an issue to a CAPA board to 11 determine whether a CAPA should be opened. 12 Right? 13 A. It's -- yes. I guess -- I guess 14 I can agree to that, yes. The situation analysis 15 is submitted to the CAPA board to determine 16 whether it warrants a CAPA or not. 17 Q. And part of the health hazard 18 evaluation that might perhaps be an escalation of 19 a situation analysis is to determine what the 20 risk is to the patients. Correct? 21 A. Yes. 22 Q. And I want to look at -- looking 23 back at Exhibit 2, if you look at page 3 of 24 Exhibit 2, which is Bates stamped 028985 in</p>	<p>1 from an over-delivery of insulin. 2 Q. Right. So do you recall when it 3 was that you first did get involved with this 4 investigation? 5 A. I don't exactly, no. 6 Q. Okay. Well, if you look at 7 Exhibit 2 for identification, it looks like -- we 8 agreed that the date it was created was April 9 30th of 2013. And if you look at the second 10 page, it has you listed as the owner. 11 Do you see that? 12 A. That's correct. 13 Q. And your team members were Mark 14 Curtis, John Duarte, Benjamin Grover, Charlyn Lu 15 and Matt Weiner. Correct? 16 A. Correct. 17 Q. So the owner means you're the 18 leader on this. Right? 19 A. Yes. 20 Q. So when the CAPA is opened, it 21 was assigned to you. Correct? 22 A. I don't -- again, I don't 23 remember. It doesn't mean -- me being here as an 24 owner doesn't mean that I was assigned it from</p>
<p style="text-align: center;">Page 75</p> <p>1 Brackin. The "Priority Rationale" here for this 2 CAPA "was set as high due to the following 3 reasons: Product is in the field" and "Patient 4 safety risk is high do to the following reasons." 5 Do you see that? 6 A. I do. 7 Q. And did you understand that the 8 evaluation of the risk to patients was the -- the 9 danger was considered to be severe, even if the 10 risk was low that it would occur? 11 MR. MERRELL: Objection to form. 12 THE WITNESS: The consequences of 13 this phenomenon can be severe, yes, I 14 will agree to that. 15 BY MR. HAVERTY: 16 Q. And that's because it could lead 17 to the unintended and unknown -- unintentional 18 delivery -- over-delivery of insulin into a 19 patient's body. Correct? 20 A. Correct. 21 Q. And that could lead to either 22 coma or death ultimately. Right? 23 A. Yes. I'm not a medical 24 professional, but yes. Nothing good can come</p>	<p style="text-align: center;">Page 77</p> <p>1 the beginning. Owners do change on CAPAs, and 2 these documents do change. 3 Q. Do you recall how it was you 4 first got involved with this CAPA? 5 A. I do. Yeah. I got called into a 6 meeting to quality -- one of the quality 7 directors at the time and was presented with this 8 project and asked to -- or assigned to take the 9 lead on this. 10 Q. Do you recall anything else you 11 were told about that? 12 A. About what, I'm sorry? 13 Q. Yeah. Did you -- what did you 14 understand the reason the CAPA was being opened? 15 A. The reason for -- for that is the 16 risk is high and despite the occurrence being 17 low, and there is something that makes this 18 happen, and we need to investigate and alleviate 19 it. 20 Q. And did you have an understanding 21 at that point in time what the problem was, what 22 the risk was? 23 A. What the risk was and what the 24 problem was, yes.</p>

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<p>1 Q. So at that point when you got 2 involved, had the investigation already been 3 done, they identified the problem, they 4 replicated it, they had done all that 5 investigation, and they realized that a CAPA 6 needed to be opened?</p> <p>7 A. Correct.</p> <p>8 Q. At the time when you got called 9 into this meeting, had the CAPA been opened at 10 that point or would you be -- were you discussing 11 this because there was an intent to submit it to 12 the CAPA board? Do you recall?</p> <p>13 A. I believe it had been opened by 14 then.</p> <p>15 Q. Okay. And do you recall why it 16 is you were assigned to it?</p> <p>17 A. Because that fell into my direct 18 responsibility from a product and process and 19 supplier relationship perspective.</p> <p>20 Q. And what did you do initially 21 when you got involved in this CAPA? What steps 22 did you take?</p> <p>23 A. Hard to remember, but we set 24 occurring meetings, and we started looking at</p>	<p>1 (A discussion off the record 2 occurred.) 3 - - - 4 BY MR. HAVERTY: 5 Q. Do you have that there? 6 A. I do, yes. 7 Q. Okay. It's a PowerPoint slide 8 deck. Correct? 9 A. Correct. 10 Q. Have you ever seen this 11 PowerPoint slide deck before? 12 A. I do not remember. 13 Q. You don't know who prepared it, 14 do you? 15 A. I don't. 16 Q. Do you recall whether there was 17 a -- any type of a presentation, a meeting, about 18 the prime/fill anomaly review in March of 2013? 19 A. I don't remember that. 20 Q. Okay. Go on to the second -- 21 second page. And it gives a "Background." It 22 says, "Complaints from Europe on Insulin dripping 23 out prior to plunger touching the Stopper." And 24 it's, "Video sent from a Customer in Germany."</p>
<p>1 different things. We started pulling team 2 members in, and essentially started investigating 3 in many different directions.</p> <p>4 Q. If you could take a look, please, 5 at Exhibit 8.</p> <p>6 - - -</p> <p>7 (Deposition Exhibit No. AA-8, 8 PowerPoint, "Prime/Fill Anomaly Review 9 3-21-13," Bates stamped MDT-BRACP-0067966 10 through MDT-BRACP-0067973, was marked for 11 identification.)</p> <p>12 - - -</p> <p>13 MR. MERRELL: 8.</p> <p>14 THE WITNESS: 8, I'm sorry?</p> <p>15 BY MR. HAVERTY:</p> <p>16 Q. 8. Yes, 8.</p> <p>17 A. 8.</p> <p>18 Q. Do you have it there?</p> <p>19 A. Almost.</p> <p>20 MR. MERRELL: Sorry, we're just 21 fiddling with the binder.</p> <p>22 THE WITNESS: Dealing with a 23 malfunctioning binder.</p> <p>24 - - -</p>	<p>1 And then, "Customer's sets arrived for analysis 2 1-31-13." And then, "P-cap Vent flow tested and 3 found to be in spec." And then, "Detailed 4 engineering investigation by Mark Curtis and 5 January Duarte through February." 6 Do you see that? 7 A. Yes. 8 Q. And that's what we were just 9 talking about a few minutes ago, correct, the 10 sequence of events that occurred from the 11 complaint in September of 2012. Right? 12 A. It appears so, yes. 13 Q. And is that consistent with your 14 recollection of the events as they unfolded? 15 A. Again, I have a hard time 16 remembering this, because I don't think I was 17 involved in this project at that time. 18 Q. But at some point when you did 19 get involved in it, you learned about the 20 historical events. Correct? 21 A. Correct. 22 Q. And what was just described 23 there, is that consistent with what your 24 understanding was of the history?</p>

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<p>1 A. Yes, correct.</p> <p>2 Q. And then the next page, it's</p> <p>3 "Engineering Analysis Results." And it says,</p> <p>4 "Root Cause Identified: Insulin drops wetting</p> <p>5 the membrane from inside create temporary block</p> <p>6 of membrane. Drops are most likely formed via</p> <p>7 improper reservoir filling technique." And</p> <p>8 "Preliminary experiments indicate a wet membrane</p> <p>9 may take 5 minutes to over 30 minutes to dry out</p> <p>10 while in the pump."</p> <p>11 Do you see that?</p> <p>12 A. I do.</p> <p>13 Q. And it makes reference to a</p> <p>14 video. There was a video that Mark Curtis had</p> <p>15 made demonstrating this.</p> <p>16 Is that your recollection?</p> <p>17 A. Yes, correct.</p> <p>18 Q. All right. And then the next</p> <p>19 point is, "Confirmation of Customer case." It</p> <p>20 was a "Test to detect dry insulin on the membrane</p> <p>21 developed." And then "Traces of dried insulin</p> <p>22 were identified on the returned sets."</p> <p>23 Do you recall we talked about</p> <p>24 that earlier?</p>	<p>1 Q. And the problem that they had</p> <p>2 with that is the prime/fill anomaly, the EA05</p> <p>3 code, was generic to more than just one</p> <p>4 particular problem. Correct?</p> <p>5 MR. MERRELL: Objection to form.</p> <p>6 MS. MARTINEZ: Objection.</p> <p>7 THE WITNESS: That is correct.</p> <p>8 BY MR. HAVERTY:</p> <p>9 Q. So that's why it was difficult</p> <p>10 for them to determine what the actual incidence</p> <p>11 of this phenomenon was based upon the complaints</p> <p>12 and the coding. Right?</p> <p>13 MR. MERRELL: Objection to form.</p> <p>14 THE WITNESS: Yes. That is</p> <p>15 correct.</p> <p>16 BY MR. HAVERTY:</p> <p>17 Q. And we're going to get into this</p> <p>18 in a little bit more detail.</p> <p>19 As a result of that, a new code</p> <p>20 was developed that was specific to this temporary</p> <p>21 vent blockage phenomenon. Correct?</p> <p>22 A. Correct.</p> <p>23 Q. Now, it's captioned at the bottom</p> <p>24 there, it says, "About 20% of complaints" -- this</p>
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<p>1 A. Yes, I do.</p> <p>2 Q. So that was consistent with what</p> <p>3 the history was that you learned about this</p> <p>4 phenomenon. Correct?</p> <p>5 A. Yes.</p> <p>6 Q. And then go to the next page, if</p> <p>7 you would.</p> <p>8 This is a line graph that I</p> <p>9 believe you had -- you had somebody make for you.</p> <p>10 Correct?</p> <p>11 A. Again, I don't remember if it was</p> <p>12 made at my request or it was made prior to that.</p> <p>13 Q. Okay. Well, you see that it has</p> <p>14 the "Occurrence Rate" of "Prime Fill Anomaly EA05</p> <p>15 Complaint Count" from January 2011 to February</p> <p>16 2013.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And by the way, let's talk a</p> <p>20 little bit about that.</p> <p>21 One of the issues that came up</p> <p>22 was the issue of the coding of these complaints</p> <p>23 as prime/fill anomaly. Correct?</p> <p>24 A. Correct.</p>	<p>1 would be of the EA05 complaint code -- "indicate</p> <p>2 insulin dripping without plunger touching."</p> <p>3 Do you recall that assessment?</p> <p>4 A. No, I don't.</p> <p>5 Q. Do you -- if you note that</p> <p>6 there's a beginning upward trend in these</p> <p>7 complaints beginning it looks like in around</p> <p>8 January of 2012, peaking in about October of</p> <p>9 2012.</p> <p>10 Do you see that?</p> <p>11 MR. MERRELL: Objection to form.</p> <p>12 THE WITNESS: I can see that on</p> <p>13 the graph, yes.</p> <p>14 BY MR. HAVERTY:</p> <p>15 Q. Do you have any idea why they</p> <p>16 would have began that upward trend and peaking</p> <p>17 ultimately in October of 2012?</p> <p>18 A. No, I don't.</p> <p>19 Q. Okay. If you go to the next</p> <p>20 page, it says, "Patient Risk - Known Cases of</p> <p>21 Harm." And it says, first bullet point,</p> <p>22 "Reviewed SVN's for the period of January 2011 to</p> <p>23 February 2013, for primary-fill anomaly and Low</p> <p>24 Blood Glucose (both hospitalized and non</p>

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<p style="text-align: right;">Page 86</p> <p>1 hospitalized) codes."</p> <p>2 Next bullet point, "Additional</p> <p>3 legal received from Legal."</p> <p>4 Next bullet point, "5 instances</p> <p>5 of customers experiencing inside Low Blood</p> <p>6 Glucose" at -- "(at varying levels of severity)</p> <p>7 were identified during the period." And then,</p> <p>8 "Details are tabulated in the next page."</p> <p>9 And then it goes on and says,</p> <p>10 last bullet point, "Annual Occurrence is</p> <p>11 estimated at 91 cases per year," and that's "(20%</p> <p>12 times 457), or" about "0.02% of Active base</p> <p>13 (425,000), which is a Rare Occurrence."</p> <p>14 Do you see that?</p> <p>15 A. I do.</p> <p>16 Q. Okay. Were you aware of that</p> <p>17 information around the time you got involved in</p> <p>18 this?</p> <p>19 A. No. I was aware of the five</p> <p>20 instances of customers experiencing low BG.</p> <p>21 Q. Okay.</p> <p>22 A. But not about the rest of the</p> <p>23 data here.</p> <p>24 Q. You were not aware of the</p>	<p style="text-align: right;">Page 88</p> <p>1 but five occurrences. Yes.</p> <p>2 Q. Right. Because two of them don't</p> <p>3 have an associated SVN. Correct?</p> <p>4 A. Correct.</p> <p>5 Q. For whatever reason, nobody</p> <p>6 knows, I guess. Right?</p> <p>7 A. Correct.</p> <p>8 Q. But anyway, the first one was</p> <p>9 from September of 2012, and it notes that the</p> <p>10 complaint was "Low Blood Glucose Not</p> <p>11 hospitalized, suspected 50 units of over</p> <p>12 delivery."</p> <p>13 Do you see that?</p> <p>14 A. I do.</p> <p>15 Q. And I think you said, you do</p> <p>16 remember the -- the information concerning the</p> <p>17 five cases that were identified. Right?</p> <p>18 A. That is correct.</p> <p>19 Q. And then the next one is dated</p> <p>20 5/23/12, "Low Blood Glucose, hospitalized,</p> <p>21 Suspected 80 units" of "over-delivery."</p> <p>22 Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. And by the way, 50 units or</p>
<p style="text-align: right;">Page 87</p> <p>1 estimate of 91 cases per year, this phenomenon?</p> <p>2 A. No. I don't remember those</p> <p>3 numbers.</p> <p>4 Q. Okay. Did you at some point</p> <p>5 become aware of that?</p> <p>6 A. I did, but, again, maybe not</p> <p>7 about those numbers exactly.</p> <p>8 Q. Okay. And by the way, going back</p> <p>9 to where we identified the SVNs, those are</p> <p>10 service notifications. Correct?</p> <p>11 A. Correct.</p> <p>12 Q. And those are documents that are</p> <p>13 created when a customer calls in with a</p> <p>14 complaint. Correct?</p> <p>15 A. Correct.</p> <p>16 Q. And they each have their own</p> <p>17 unique number. Right?</p> <p>18 A. Right.</p> <p>19 Q. If you go to the next page,</p> <p>20 please, and it lists the five SVNs, correct, that</p> <p>21 were identified where patients were hospitalized</p> <p>22 or had low blood glucose and were either</p> <p>23 hospitalized or not hospitalized. Right?</p> <p>24 A. Right. I only see three numbers</p>	<p style="text-align: right;">Page 89</p> <p>1 80 units of over-delivery would be a pretty large</p> <p>2 dose of insulin, would it not?</p> <p>3 A. Not exactly sure about dosage.</p> <p>4 Q. Okay. It would probably depend</p> <p>5 upon the individual patient. Right?</p> <p>6 A. Correct. Again, I'm not a</p> <p>7 medical professional, so I cannot really make</p> <p>8 those assessments.</p> <p>9 Q. Okay. Then the next one is from</p> <p>10 February 22nd of 2011, and it's listed as a "Low</p> <p>11 Blood Glucose, hospitalized, suspected 200 units"</p> <p>12 of "over-delivery. Deceased a month later,</p> <p>13 correlation to be determined" and "Litigation</p> <p>14 Pending."</p> <p>15 Do you see that?</p> <p>16 A. I do.</p> <p>17 Q. Do you ever recall any</p> <p>18 conversations about any of these five cases?</p> <p>19 Were you ever involved in any discussions?</p> <p>20 A. These five cases, if I remember,</p> <p>21 they're mentioned in the CAPA, and the CAPA was</p> <p>22 actually opened based on these five cases.</p> <p>23 Q. Okay. And -- okay. That's an</p> <p>24 interesting point that you make.</p>

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<p style="text-align: right;">Page 90</p> <p>1 What about these five cases drove 2 the decision to open a CAPA?</p> <p>3 A. The -- I guess the severity of 4 these five cases.</p> <p>5 Q. Right. And that's -- in fact, 6 you've got one that was hospitalized with 7 200 units of over-delivery who died a month 8 later. Right?</p> <p>9 A. Yes. Suspected 200 units, yes.</p> <p>10 Q. Yeah. And then the fourth case 11 that's listed is from June of 2012, and it has 12 "Low Blood Glucose, Hospitalized, suspected 13 85 units" of "over-delivery."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And then the final one is from 17 March of 2013, "Low Blood Glucose not 18 hospitalized, suspected 75 units" of 19 "over-delivery."</p> <p>20 Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. Do you recall a situation where a 23 customer reported to Anthony Vicente that he 24 had -- that he had filled his reservoir,</p>	<p style="text-align: right;">Page 92</p> <p>1 this CAPA?</p> <p>2 A. On some other projects. Anthony 3 Vicente takes care of SVN's, and sometimes there's 4 data needed for this project or that project that 5 only can come from him or people working in the 6 same department with him.</p> <p>7 Q. Okay. If you could go to the 8 next page on Exhibit 8, so this appears to be a 9 type of a risk assessment. Correct?</p> <p>10 A. Looks like it, yes.</p> <p>11 Q. Okay. Are you able to tell from 12 this matrix what the estimated risk assessment 13 was for this prime/fill anomaly? Is there any 14 way to tell?</p> <p>15 A. No, no, not really.</p> <p>16 Q. Okay. If you look up at the top 17 there, it's got "A33 - Loose Cap only Annual 18 Frequency 0.3%."</p> <p>19 Do you know what that's referring 20 to?</p> <p>21 A. I do.</p> <p>22 Q. What is it referring to?</p> <p>23 A. So A33 is a -- is a failure -- 24 let's call it a failure code that is produced by</p>
<p style="text-align: right;">Page 91</p> <p>1 attempted to prime his pump, and it only primed a 2 couple of units when he expected 8 or 9 units, 3 and that he woke up in the middle of the night 4 and saw that his reservoir was empty? Do you 5 recall that?</p> <p>6 A. I recall that somebody made a 7 complaint directly to Anthony Vicente at some 8 social event or sports game. I don't exactly 9 remember the details of the complaint.</p> <p>10 Q. Do you know whether that was the 11 March 14, 2013 SVN that's listed there as case 12 number 5?</p> <p>13 A. No. Like I said, I don't 14 remember the exact SVN that that resulted in.</p> <p>15 Q. And during the course of your 16 work on the CAPA, in the investigation, did you 17 have interactions with Anthony Vicente?</p> <p>18 A. Of course.</p> <p>19 Q. Prior to this time, your 20 involvement in the CAPA, did you have any 21 interactions with Anthony Vicente?</p> <p>22 A. Yes.</p> <p>23 Q. Why would you have a reason to 24 interact with Anthony Vicente other than outside</p>	<p style="text-align: right;">Page 93</p> <p>1 the pump, I assume. And what I remember, there 2 was a -- there was a project around that.</p> <p>3 Q. Was there a CAPA, to your 4 knowledge?</p> <p>5 A. I think there was a CAPA. And I 6 actually may have been briefly involved in that 7 CAPA, very briefly.</p> <p>8 Q. And what was your involvement in 9 that CAPA?</p> <p>10 A. I did some experiments on that 11 while -- while they were looking for another 12 engineer to take that over.</p> <p>13 Q. And what experiments did you do?</p> <p>14 A. So a loose cap test has to do 15 with a portion of a pump housing that may become 16 loose, and we did some experiments on different 17 geometry on that.</p> <p>18 Q. Now, on this risk matrix, it 19 doesn't look like there's any evaluation of the 20 risk from the prime/fill anomaly. Correct?</p> <p>21 A. Correct. Not obvious, yes.</p> <p>22 Q. Okay. If you go to the next 23 page, again, it doesn't appear to be any analysis 24 of the risk specific to the prime/fill anomaly.</p>

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<p style="text-align: right;">Page 94</p> <p>1 Correct?</p> <p>2 A. Correct.</p> <p>3 Q. And I think you said that you --</p> <p>4 the CAPA had already been open -- you think the</p> <p>5 CAPA was already opened by the time you got</p> <p>6 involved in it?</p> <p>7 A. That is correct.</p> <p>8 Q. Do you know who presented to the</p> <p>9 CAPA board in order to get a CAPA open?</p> <p>10 A. No, I do not.</p> <p>11 Q. What was the -- anyway, if you</p> <p>12 could go back to Exhibit 2, to the CAPA -- the</p> <p>13 complete CAPA file.</p> <p>14 A. Uh-huh. Yes.</p> <p>15 Q. And look on page 2, the second</p> <p>16 page, under "Mitigation Comments," it says, "A</p> <p>17 Health Hazard Evaluation...2013-03...was</p> <p>18 performed to assess the risks and evaluate</p> <p>19 potential risk mitigation methods. The following</p> <p>20 steps were identified to be needed in order to</p> <p>21 mitigate the risk at hand."</p> <p>22 First bullet point, "Customer</p> <p>23 communication letter-sent to current US Paradigm</p> <p>24 pump users."</p>	<p style="text-align: right;">Page 96</p> <p>1 part of the CAPA, that there would be a</p> <p>2 preventative process designed to look at how you</p> <p>3 could mitigate the hazard entirely?</p> <p>4 A. When you refer to discussions, at</p> <p>5 what point of time and at what -- in what</p> <p>6 settings?</p> <p>7 Q. Well, when the CAPA was opened,</p> <p>8 what was the intent at that point, do you know?</p> <p>9 A. Again, I don't remember, because</p> <p>10 I think CAPA was opened before my involvement.</p> <p>11 Q. Okay. Well, did you come to</p> <p>12 understand what the purpose of the CAPA was once</p> <p>13 you got involved?</p> <p>14 A. Yes.</p> <p>15 Q. And what was the purpose of the</p> <p>16 CAPA?</p> <p>17 A. CAPA -- purpose of the CAPA was</p> <p>18 to investigate and potentially implement</p> <p>19 something that will completely eliminate this</p> <p>20 phenomenon from -- from happening, or at least</p> <p>21 mitigate it to the point of very, very low</p> <p>22 occurrence.</p> <p>23 Q. Right. And what we're talking</p> <p>24 about here in the mitigation comments, and we</p>
<p style="text-align: right;">Page 95</p> <p>1 Next bullet point, "Healthcare</p> <p>2 Professional Letter-sent to physicians who have</p> <p>3 prescribed Paradigm pumps."</p> <p>4 Next bullet point, "Distributor</p> <p>5 letter-sent to distributors and payers."</p> <p>6 Next bullet point, "Wholesale</p> <p>7 letter-sent to wholesale partners."</p> <p>8 And last bullet point, "In</p> <p>9 addition to all communications, a package insert</p> <p>10 is included with shipments of Paradigm pumps,</p> <p>11 reservoirs and Paradigm Infusion sets."</p> <p>12 Do you see that?</p> <p>13 A. I do.</p> <p>14 Q. Okay. Would you agree with me</p> <p>15 that that was intended as the corrective</p> <p>16 action -- the corrective part of a corrective and</p> <p>17 preventative action?</p> <p>18 MR. MERRELL: Objection to form.</p> <p>19 THE WITNESS: It was the initial</p> <p>20 corrective action. Yes, I would agree</p> <p>21 with that.</p> <p>22 BY MR. HAVERTY:</p> <p>23 Q. And was there a discussion that</p> <p>24 in addition to the initial part of the corrective</p>	<p style="text-align: right;">Page 97</p> <p>1 talked about that's the corrective part of the</p> <p>2 process, these would all fall under the category</p> <p>3 of the type of warnings that you would use for</p> <p>4 risk mitigation. Correct?</p> <p>5 A. Correct.</p> <p>6 Q. And again, as we talked about,</p> <p>7 that's the least preferred method of risk</p> <p>8 mitigation, if you can design the hazard out or</p> <p>9 if you can guard against the hazard. Correct?</p> <p>10 MR. MERRELL: Objection to form.</p> <p>11 THE WITNESS: Again, it's -- it's</p> <p>12 depending on the situation. I --</p> <p>13 there's -- I can't -- I can't say whether</p> <p>14 one is more important or more effective</p> <p>15 than another.</p> <p>16 BY MR. HAVERTY:</p> <p>17 Q. Okay.</p> <p>18 A. It really all depended.</p> <p>19 Q. Anyway, going back to the next</p> <p>20 page, we talked about this, I didn't finish up,</p> <p>21 I'm sorry for jumping around, we talked about the</p> <p>22 "Priority Rationale...was set as high due to the</p> <p>23 following reasons: " The "product is in the</p> <p>24 field," which means patients are being exposed to</p>

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<p style="text-align: right;">Page 98</p> <p>1 it. Correct?</p> <p>2 A. Correct.</p> <p>3 Q. And then "Patient safety risk is</p> <p>4 high do to the following reasons," and that's</p> <p>5 when we talked about the risk was relatively --</p> <p>6 the severity of the risk was important. Correct?</p> <p>7 A. Correct.</p> <p>8 Q. And that's because "The failure</p> <p>9 can potentially result in over delivery of</p> <p>10 insulin leading to patient hospitalization" and</p> <p>11 "The failure can potentially result in under</p> <p>12 delivery of" insulation -- "insulin leading to</p> <p>13 patient hospitalization."</p> <p>14 Do you see that?</p> <p>15 A. I do.</p> <p>16 Q. Now, we talked a little bit about</p> <p>17 how the over-delivery could occur, based upon the</p> <p>18 videos and what was shown in the videos.</p> <p>19 Can you describe for us how the</p> <p>20 failure or the blocking of the vents could</p> <p>21 potentially result in an under-delivery of</p> <p>22 insulin?</p> <p>23 A. To the best of my knowledge, once</p> <p>24 the phenomenon occurs and then pressure finally</p>	<p style="text-align: right;">Page 100</p> <p>1 large the gap is between the slide screw and the</p> <p>2 reservoir stopper when the reservoir stopper</p> <p>3 stops. Right?</p> <p>4 A. That is correct.</p> <p>5 Q. Now, one of the things -- if you</p> <p>6 could look at page 8 of the -- of Exhibit 2.</p> <p>7 Actually, go back to page 6.</p> <p>8 Let's go there and lay a better foundation.</p> <p>9 - - -</p> <p>10 (A discussion off the record</p> <p>11 occurred.)</p> <p>12 - - -</p> <p>13 BY MR. HAVERTY:</p> <p>14 Q. Okay. All the way at the bottom,</p> <p>15 do you see that? It says, "It is concluded that</p> <p>16 based upon the above described testing and</p> <p>17 observations," which we talked about a little</p> <p>18 earlier, "the prime/fill anomaly is caused by a</p> <p>19 blocked membrane and a contributing cause being</p> <p>20 the Reservoir filling process where an incorrect</p> <p>21 filling process can result in a blocked membrane.</p> <p>22 The contributing cause of an incorrect filling</p> <p>23 process will not be addressed as the filling</p> <p>24 process is dependent on the user and when the IFU</p>
<p style="text-align: right;">Page 99</p> <p>1 equalizes in the chamber, the pump will continue</p> <p>2 to drive the piston or the slide, by the slide</p> <p>3 not being engaged to the stopper on the reservoir</p> <p>4 will not result in any delivery of insulin.</p> <p>5 Q. And that's because when the</p> <p>6 reservoir stopper begins to move on its own and</p> <p>7 the slide screw has to basically chase -- chase</p> <p>8 after it to catch up, there will be a gap between</p> <p>9 them. Correct?</p> <p>10 A. Correct.</p> <p>11 Q. So --</p> <p>12 A. There is no physical connection</p> <p>13 between the -- between the slide of the pump and</p> <p>14 the plunger or stopper of the reservoir.</p> <p>15 Q. So what could happen is that the</p> <p>16 reservoir moves to a certain point ahead of the</p> <p>17 slide screw, stops when the pressure equalizes,</p> <p>18 and then there's a lag from the slide screw, and</p> <p>19 it takes some period of time for it to catch up</p> <p>20 before it can continue to deliver insulin.</p> <p>21 Correct?</p> <p>22 A. That is correct.</p> <p>23 Q. And it all depends upon -- how</p> <p>24 long that period of time is all depends upon how</p>	<p style="text-align: right;">Page 101</p> <p>1 is followed correctly there should not be any</p> <p>2 issues during the reservoir fill process. For</p> <p>3 this reason, this CAPA will only address the</p> <p>4 prime/fill anomaly caused by a blocked membrane.</p> <p>5 The blockage is most likely caused by a liquid</p> <p>6 (insulin or other) being present on the polyester</p> <p>7 side of the membrane. Liquid, when present on</p> <p>8 the polyester side of the membrane, seems to</p> <p>9 render the membrane impermeable to air which, in</p> <p>10 turn, traps air contained in the reservoir</p> <p>11 compartment of the pump. During a manual</p> <p>12 primary/fill cycle, the trapped air inside the</p> <p>13 pump housing gets pressurized and causes a</p> <p>14 premature movement of the reservoir plunger.</p> <p>15 Based on all factors and investigation results,</p> <p>16 the team concluded that the primary root cause</p> <p>17 for the temporary blocked P-cap membrane is" the</p> <p>18 "membrane material itself."</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. Okay. And that membrane material</p> <p>22 is part of the design of the P-cap. Correct?</p> <p>23 A. Correct.</p> <p>24 Q. So the goal of the CAPA then was</p>

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<p>1 you were not going to address the IFUs, or the 2 information for users, which would be sort of 3 like along the lines of a warning, you were going 4 to redesign the materials in the connector cap to 5 make sure that they could remain gas permeable in 6 the event that someone does fill a reservoir 7 improperly and insulin gets on the inside of the 8 cap. Right?</p> <p>9 MR. MERRELL: Objection to form. 10 THE WITNESS: Right. So 11 partially due to the fact that IFUs had 12 been updated by this point in time with 13 warnings and we, team, company, did not 14 believe that that is good enough. So we 15 decided to take one step further and 16 change something design-wise to either 17 completely eliminate this from occurring, 18 although you really can't theoretically, 19 but at least take the possibility of 20 occurrence to some minuscule number.</p> <p>21 BY MR. HAVERTY: 22 Q. And I think you just said 23 something that was important for me to follow up 24 on.</p>	<p>1 possibility of hazard occurring. Yes. 2 MR. HAVERTY: Cliff, do you want 3 to take a real quick break here? 4 MR. MERRELL: Sure. 5 THE VIDEOGRAPHER: We are now 6 going off the record, and the time is 7 11:36 a.m. 8 - - - 9 (A recess was taken from 11:36 10 a.m. to 11:57 a.m.) 11 THE VIDEOGRAPHER: We are now 12 going back on the record, and the time is 13 11:57 a.m. 14 BY MR. HAVERTY: 15 Q. Mr. Aleksandrovich, if you could 16 look at Exhibit 1, please, pull that up. 17 I just want to lay a foundation 18 for this. 19 - - - 20 (Deposition Exhibit No. AA-1, 21 Slide, "P-cap Infusion Sets Prime Fill 22 Anomaly CAPA PR#158416," Bates stamped 23 MDT-BRACP-029894, was marked for 24 identification.)</p>
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<p>1 And that is that when you 2 evaluated the mechanism of the failure mode and 3 you understood how it could occur, you didn't 4 believe that updating the IFUs and providing 5 warnings was sufficient or adequate to mitigate 6 this risk. Correct?</p> <p>7 MR. MERRELL: Objection to form. 8 THE WITNESS: Not to 100 percent 9 of -- to take care of problem.</p> <p>10 BY MR. HAVERTY: 11 Q. Right. Because the IFUs and this 12 filling process, this improper filling process, 13 all involved humans who could easily make 14 mistakes through inadvertence or inattention. 15 Right?</p> <p>16 A. Correct. 17 Q. So what you wanted to do was to 18 make sure that to the extent you could was to 19 design out the hazard entirely. Right?</p> <p>20 A. That is correct. 21 Q. And not rely upon -- 22 A. But -- 23 Q. I'm sorry. Go ahead. 24 A. Correct. To design out the</p>	<p>1 - - - 2 BY MR. HAVERTY: 3 Q. Got that? 4 A. Yes, I do. 5 Q. Do you recognize this timeline? 6 A. No. I've never seen this 7 timeline. 8 I stand corrected. I recognize 9 the timeline. I've never seen this particular 10 slide. 11 Q. Okay. So you didn't create this. 12 Correct? 13 A. I didn't. 14 Q. Could you just take a moment to 15 review it, because I want to use this as a 16 foundation for some questioning, you know, along 17 the way. 18 And just take a look at the 19 timeline and see if it comports with your 20 recollection of the events related to this CAPA. 21 MR. MERRELL: It's actually 22 really hard to read -- 23 THE WITNESS: Yeah, it is very 24 hard to read.</p>

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<p>1 MR. HAVERTY: Yeah, I know it is. 2 MR. MERRELL: -- Kevin. 3 MR. HAVERTY: I know it is, and I 4 apologize for that, but that's how it 5 came to me. 6 MS. MARTINEZ: Here. 7 MR. MERRELL: Do you want look -- 8 there's another version. 9 Do you want to look on a 10 computer, it might be easier to see? 11 MR. HAVERTY: Oh, okay. 12 MR. MERRELL: Would that be 13 helpful. 14 MR. HAVERTY: I didn't think it 15 was easier to see on the computer. 16 THE WITNESS: I can see most of 17 it. Some things there's just -- 18 MR. MERRELL: It may not be. I'm 19 just offering it. It's at least larger. 20 MR. HAVERTY: Yeah. You just 21 need to have your prescription checked, 22 Cliff. 23 THE WITNESS: No, no. It's okay. 24 Resolution gets lost anyways.</p>	<p>1 before May of 2013. Right? 2 A. Correct. 3 Q. And then there's a field 4 corrective action/health hazard evaluation noted 5 in May of 2013. Right? 6 A. Correct. 7 Q. And that's one of the things that 8 led to -- strike that. 9 Then it looks like May into -- 10 sometime in early May there's an "Extension 11 Request #1" for the "Investigation Phase, 12 Extension to summarize root cause findings in ER. 13 New due date: 6/28/13." 14 Do you recall that? 15 A. I don't recall that, but I see 16 that and I can understand what this refers to. 17 Q. I was going to ask you that. 18 What does it refer to? Why was an extension 19 needed? 20 A. Because sometimes the originally 21 planned time for certain tasks is not sufficient 22 enough and -- due to many things, possible 23 things. 24 Q. Okay. The -- I'm sorry.</p>
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<p>1 MR. HAVERTY: I spent about a 2 half an hour trying to make sure that I 3 got the maximum resolution, because I 4 agree, it's terrible. 5 THE WITNESS: Good to go. 6 BY MR. HAVERTY: 7 Q. Yeah, I noted, just for the 8 record, that you made some notes on that copy? 9 A. I did. 10 Q. What did you put on there? Just 11 so we can have it on the record. 12 A. Just abbreviations -- just 13 abbreviations to understand -- so I can 14 understand what those blocks are. Not very good 15 to see. 16 Q. Okay. But does that comport with 17 what your recollection of the timeline was for 18 the development of the new membrane material? 19 A. It does. 20 Q. I just want to put that aside for 21 right now but use that as a handy touchstone 22 for -- for going forward. 23 Before we do that, excuse me, it 24 notes that the CAPA start date was sometime</p>	<p>1 So does that mean that you didn't 2 anticipate being able to identify the root cause 3 from the engineering report until the end of June 4 of 2013? 5 A. That means that whoever filed 6 that extension, it might have been me, it might 7 have been somebody else, I don't recall at this 8 moment, that means that whoever did that needed 9 more time to finish thorough investigation. 10 Q. And to determine -- to come to a 11 conclusion about what the root cause was of the 12 problem. Correct? 13 A. True, yes. 14 Q. Okay. And then it looks like the 15 root cause was identified at the end of June, 16 consistent with that extension request. It's a 17 big yellow box. Right? 18 A. Correct. 19 Q. And it says -- yeah. It says, 20 "Root Cause. The primary/fill anomaly is caused 21 by a blocked membrane. The blockage is most 22 probably caused by a liquid (insulin or other) 23 being present on the polyester side of the 24 membrane. Liquid, when present on the polyester</p>

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<p style="text-align: right;">Page 110</p> <p>1 side of the membrane, seems to render the 2 membrane impermeable to air which, in turn, traps 3 air contained in the reservoir compartment of the 4 pump. During a manual primary/fill cycle, the 5 air trapped inside the pump housing gets 6 pressurized and causes a premature movement of 7 the reservoir plunger."</p> <p>8 Is that your recollection of what 9 the root cause was that was ultimately 10 identified?</p> <p>11 A. Yes. As documented.</p> <p>12 Q. Okay. If you could -- and I 13 apologize for bouncing around, but if you could 14 go back to Exhibit 2, please, the CAPA report, 15 and I want to direct your attention to page 4.</p> <p>16 On the heading it's 17 "Investigation Summary."</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And then, "Investigation started 21 with testing of the returned infusion sets and, 22 also, some testing of similar products."</p> <p>23 You see we talked about that a 24 little bit earlier, right, the returned products</p>	<p style="text-align: right;">Page 112</p> <p>1 says, "As it was discovered from the 2 investigation during QIR09-006, the blocked 3 membrane was caused by a deposit of silicone 4 oil."</p> <p>5 That's the Lot 8 situation, is it 6 not?</p> <p>7 A. It is.</p> <p>8 Q. It says, "This oil has been 9 removed from the manufacturing process. Also, 10 all questionable units returned during 11 investigation phase of QIR09-006 remained blocked 12 after return to Medtronic. Contrary to that, all 13 units returned during investigation phases of 14 this project demonstrated acceptable flow through 15 the P-cap membrane when tested in MiniMed's lab. 16 However, during the testing, the person 17 performing the test noticed a small green diluent 18 stain, inside the P-cap, on the polyester layer 19 of the membrane."</p> <p>20 And then it goes on to say, 21 "(Green diluent is a test media of choice in 22 MiniMed's lab environment.) Upon close review of 23 the stain it was determined that the stain was 24 residual diluent spilled onto the reservoir's</p>
<p style="text-align: right;">Page 111</p> <p>1 from Europe?</p> <p>2 A. Right.</p> <p>3 Q. And then the next paragraph says, 4 "Based on historic knowledge (CAPA QIR09-006), it 5 is known from the failure like the one reported 6 by the end user (insulin flow prior to physical 7 engagement between the pump plunger and" the 8 "reservoir stopper) is caused by a completely or 9 partially blocked vent membrane on the P-cap."</p> <p>10 Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. That -- when you're talking about 13 based on historic knowledge and identifying that 14 CAPA there from '09, is that -- is that referring 15 to the Lot 8 CAPA?</p> <p>16 A. I'm not sure what this CAPA 17 number refers to and what this CAPA number is 18 assigned to.</p> <p>19 Q. Are you aware of what the 20 historic knowledge is that they're referring to?</p> <p>21 A. Yes. That is Lot 8 related, the 22 historic knowledge, the description of the 23 failure mode.</p> <p>24 Q. Right. Yeah. So it goes on, it</p>	<p style="text-align: right;">Page 113</p> <p>1 Snapcap during filling from the insulin vial, and 2 when P-cap was attached over the Snapcap, the 3 green diluent was transferred onto the membrane 4 inside the P-cap."</p> <p>5 You recall that was the Mark 6 Curtis situation. Correct?</p> <p>7 A. Correct.</p> <p>8 Q. And it resulted from Mark Curtis 9 actually performing the same improper filling 10 process as some of the other patients who had 11 complained about the prime/fill anomaly.</p> <p>12 Correct?</p> <p>13 A. It appears so, yes.</p> <p>14 Q. So Mark Curtis, one of the -- one 15 of Medtronic's own engineers, did the same -- 16 made the same mistake as customers were making 17 that was resulting in this prime/fill anomaly.</p> <p>18 Right?</p> <p>19 MR. MERRELL: Objection to form.</p> <p>20 THE WITNESS: I'm not sure if he 21 made the same mistake during this 22 investigation. He simply observed 23 diluent. How it got there remains 24 unknown at this point.</p>

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<p style="text-align: right;">Page 114</p> <p>1 BY MR. HAVERTY:</p> <p>2 Q. Well, but it goes on, it says, 3 "Residual...spilled onto the reservoir's Snapcap 4 during filling from the insulin vial."</p> <p>5 And you know that that was 6 because it was -- the insulin vial -- excuse me, 7 the reservoir was disconnected from the transfer 8 guard while the insulin vial was on top. Right?</p> <p>9 A. Again, I am not -- I cannot 10 attest and I have no idea how exactly it happened 11 during the event described in this particular 12 paragraph.</p> <p>13 Q. Okay. If you could go to -- if 14 you go to page 8 on Exhibit 2.</p> <p>15 Do you have that?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. This page is captioned 18 "Action Summary." It has "Action Plan: The goal 19 of the CAPA is to eliminate the possibility of 20 the PCAP venting membrane to become temporarily 21 blocked if liquid is introduced to the inside of 22 the PCAP. Membrane material replacement is 23 necessary to eliminate such issue. An alternate 24 membrane material was selected."</p>	<p style="text-align: right;">Page 116</p> <p>1 the reservoirs in the pump?</p> <p>2 A. It was discussed but quickly 3 discarded.</p> <p>4 Q. Okay. Why was it quickly 5 discarded?</p> <p>6 A. Because it's -- it is very, very 7 challenging from the engineering and 8 manufacturing standpoint.</p> <p>9 Q. Why was it challenging from an 10 engineering -- strike that. Let me make sure 11 that we're on the same page.</p> <p>12 What I'm talking about is, was it 13 discussed that there could be some type of either 14 a redundancy in the pump itself or some type of 15 redesign of the pump that would allow venting?</p> <p>16 A. To my recollection, again, it was 17 briefly discussed. And due to the difficulties 18 it would present to -- and the time frame it 19 would present to -- and try to implement 20 something like this, it was not considered as a 21 solution.</p> <p>22 Q. What time frame did they estimate 23 it would take if you were to pursue a redesign of 24 the pump itself or create a redundancy in the</p>
<p style="text-align: right;">Page 115</p> <p>1 That was the ultimate goal of the 2 CAPA, was it not?</p> <p>3 MR. MERRELL: Objection to form.</p> <p>4 THE WITNESS: The ultimate goal 5 of the CAPA was to determine a solution 6 to the problem to eliminate the root 7 cause. So this particular page states 8 that solution was identified, yes.</p> <p>9 BY MR. HAVERTY:</p> <p>10 Q. And in this particular thing, as 11 least as of the closing of this CAPA, it was -- 12 the solution that was generated was an 13 alternative membrane that could remain gas 14 permeable even when wet. Correct?</p> <p>15 A. Correct.</p> <p>16 Q. And we're going to get into this 17 a little bit, but that wasn't the only 18 alternative that was explored during the course 19 of this CAPA. Right?</p> <p>20 A. The only alternative explored as 21 a solution after investigation had completed.</p> <p>22 Q. Well, but I'm saying, but during 23 the course of the CAPA, were there other 24 alternatives that were explored, such as venting</p>	<p style="text-align: right;">Page 117</p> <p>1 pump itself that could eliminate this hazard?</p> <p>2 A. I don't remember exactly, but 3 three to five years easy.</p> <p>4 Q. And in this particular case with 5 the membrane redesign, it took over 6 three-and-a-half years. Correct?</p> <p>7 A. To completely implement it, yes.</p> <p>8 Q. Okay. But anyway, according to 9 the action plan on page 8 -- and I'm just -- I'm 10 not going to go down all of these. We'll follow 11 up a little bit later. But the first thing was 12 to "Identify Alternative Materials" and the due 13 date for that was estimated, at least as the CAPA 14 opened, October 15th of 2013. Right?</p> <p>15 A. Right.</p> <p>16 Q. And by the way, who was it that 17 set these dates? Was it you as the CAPA leader?</p> <p>18 A. At this point then, it was me, 19 yes.</p> <p>20 Q. Do you know how you settled on 21 October 15, 2013 as an expected due date for 22 identifying alternative materials?</p> <p>23 A. Based on inputs provided by 24 various team members and suppliers and my</p>

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<p>1 experience and other factors.</p> <p>2 Q. And at this point in time, had</p> <p>3 you been in contact with Unomedical concerning</p> <p>4 the issues and the need for redesign of the</p> <p>5 membrane material?</p> <p>6 MS. MARTINEZ: Object to the</p> <p>7 form. At which point in time?</p> <p>8 THE WITNESS: Yes. We were in</p> <p>9 contact with Unomedical throughout the</p> <p>10 entirety of this project.</p> <p>11 BY MR. HAVERTY:</p> <p>12 Q. And I think, without going into a</p> <p>13 whole lot of paperwork on it, but I think you</p> <p>14 were concerned about what the basic problem was</p> <p>15 with the membranes, whether it was an aging</p> <p>16 process or whether it was the manufacturing</p> <p>17 process that allowed this material to become gas</p> <p>18 impermeable if wet. Correct?</p> <p>19 A. Correct. We considered those.</p> <p>20 Q. You explored a number of</p> <p>21 different options. And then you realized that it</p> <p>22 was the material itself and not any of the</p> <p>23 manufacturing processes or the age of the</p> <p>24 material. Right?</p>	<p>1 we had on hand."</p> <p>2 And then it goes on a couple</p> <p>3 sentences later, it says, "As you can see,</p> <p>4 somewhere in 2009 we lost the ability to flow any</p> <p>5 air while wet. It is not a design requirement</p> <p>6 for the membrane but this is a phenomenon that</p> <p>7 we'd like to investigate."</p> <p>8 Do you see that?</p> <p>9 A. I do.</p> <p>10 Q. What was your working theory at</p> <p>11 that point? Did you have any idea why in 2009</p> <p>12 the ability to flow air even when wet was lost?</p> <p>13 A. Yeah. It was part of the</p> <p>14 investigation of the historical samples to</p> <p>15 determine if the -- there was a change in the</p> <p>16 material properties that caused such phenomenon.</p> <p>17 Q. And did you ultimately find that</p> <p>18 there was one or there wasn't?</p> <p>19 A. We never found if there was one.</p> <p>20 Q. Okay. So do you have any idea</p> <p>21 what it was that was unique to 2009 that you</p> <p>22 began to lose this gas permeability?</p> <p>23 A. No. We were never able to</p> <p>24 determine it.</p>
<p>1 A. Right, correct.</p> <p>2 Q. If you could look at Exhibit 15,</p> <p>3 please.</p> <p>4 - - -</p> <p>5 (Deposition Exhibit No. AA-15,</p> <p>6 Email chain, top one dated May 21, 2013,</p> <p>7 Bates stamped MDT-BRACP-0050917 through</p> <p>8 MDT-BRACP-0050922, was marked for</p> <p>9 identification.)</p> <p>10 - - -</p> <p>11 THE WITNESS: Okay.</p> <p>12 BY MR. HAVERTY:</p> <p>13 Q. Do you have that?</p> <p>14 A. Yes.</p> <p>15 Q. It's an email from you to Sara S.</p> <p>16 Harboe dated May 21, 2013.</p> <p>17 Who is Sara Harboe?</p> <p>18 A. She was -- I don't know if she</p> <p>19 still is, but she was an employee of Unomedical.</p> <p>20 Q. Do you know what her job was?</p> <p>21 A. No, I don't recall.</p> <p>22 Q. Going to the body of this, you</p> <p>23 noted, "Attached is a graph summarizing the</p> <p>24 testing we've done on the historical samples that</p>	<p>1 Q. Do I understand from that that</p> <p>2 the historic samples that you tested that were</p> <p>3 from before 2009 were still able to be gas</p> <p>4 permeable even when wet?</p> <p>5 A. Some of them were. Yes. If I</p> <p>6 remember correctly, some -- some samples were</p> <p>7 able to flow while wet, yes.</p> <p>8 Q. Okay. And was that sort of</p> <p>9 random, you know, unpredictable, or were you able</p> <p>10 to identify any particular characteristics of</p> <p>11 those sets that allowed them to remain gas</p> <p>12 permeable?</p> <p>13 A. Completely random. There was --</p> <p>14 there was no correlations determined or anything</p> <p>15 in that aspect.</p> <p>16 Q. So that would be another factor</p> <p>17 that would lead you to want to redesign the</p> <p>18 membrane material entirely, to eliminate any</p> <p>19 issue, even though some random samples could</p> <p>20 still remain gas permeable. Correct?</p> <p>21 A. That is correct.</p> <p>22 Q. Anyway, going back to Exhibit 2,</p> <p>23 the CAPA report, and back on page 8 --</p> <p>24 A. Uh-huh.</p>

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<p style="text-align: right;">Page 122</p> <p>1 Q. Step 2 on the "Action Plan" was, 2 you wanted to validate the assembly process using 3 new material, and the estimated due date for that 4 was May 30th of 2014. 5 Do you see that? 6 A. I do. 7 Q. Okay. How did you come up with 8 that date of May 30th of 2014? 9 A. Again, based on inputs from 10 customer and my team members and my experience. 11 Q. Okay. So what would happen is 12 that you would expect or you were hoping to 13 identify alternative materials by October 15th 14 and then have them completely validated in the 15 manufacturing process by the end of May of 2014, 16 about six months later. Right? 17 A. Correct. 18 Q. And when you talk about 19 validating the assembly process, does that mean 20 actually manufacturing samples of the new 21 material? 22 A. That's part of validating -- 23 Q. What else -- 24 A. -- the process.</p>	<p style="text-align: right;">Page 124</p> <p>1 there was a need to do that. 2 Q. Did you know at the time when you 3 were making this plan that there likely would be 4 some type of material out there that could remain 5 gas permeable even when wet? 6 A. I don't exactly remember the -- 7 the correlation at which point we determined that 8 there is a material out there as compared to this 9 plan. 10 Q. By the way, I should have laid 11 this foundation a little -- a long time ago. 12 But when talking about the 13 membrane material which has the vents in it on 14 the inside of the cap, it's actually a two-layer 15 material, a two-layer membrane. Correct? 16 A. The material previously used is 17 constructed that way. 18 And I would like to correct you. 19 There's no vents opening in the membrane itself. 20 Q. Right. The vents are in the cap 21 itself. Correct? 22 A. The vents are in the plastic 23 house of the P-cap, yes. 24 Q. And the membrane goes on the</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. What else is part of validating? 2 A. Part of validating is to 3 determine the process -- first of all, whether 4 there is a process, and then whether that's -- 5 that process is capable of manufacturing 6 what's -- what's expected, what in certain ranges 7 with certain outputs. And also to determine the 8 process range within -- within which we can 9 control that. 10 Q. And let me ask this question: 11 Did you -- during the course of this CAPA, did 12 you have anybody who was a materials science 13 person involved? 14 A. No. 15 Q. Okay. Are there any materials 16 science people at Medtronic? 17 A. I can't answer that question. 18 Probably there are some, but we never involved a 19 specifically materials science person in this 20 project. 21 Q. Is there a particular reason why 22 you didn't consider consulting a materials 23 science person? 24 A. Because, yeah, we didn't think</p>	<p style="text-align: right;">Page 125</p> <p>1 inside of the P-cap. Correct? 2 A. Correct. 3 Q. And it's a two-layer membrane. 4 The outside layer is a hydrophobic PTFE. 5 Correct? 6 A. On the -- we're talking about the 7 previously used membrane. 8 Q. Yes. Yeah, the one -- the one 9 that was in use back in 2013. 10 A. Yes, that is correct. 11 Q. Okay. And that's what was called 12 hydrophobic, meaning it repels water, it repels 13 moisture. Correct? 14 A. Correct. 15 Q. And the bottom layer of the 16 membrane which faces inside the cap, it was made 17 of an unwoven polyester fiber. Correct? 18 A. Correct. 19 Q. Okay. And that was the issue, it 20 was the polyester portion of it that could become 21 gas impermeable if it got wet. Correct? 22 A. That is correct. 23 Q. If you could look at -- make sure 24 I find this one. Give me one second, please.</p>

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<p style="text-align: right;">Page 126</p> <p>1 Exhibit 18, please. 2 - - - 3 (Deposition Exhibit No. AA-18, 4 Email dated June 08, 2013, Bates stamped 5 MDT-BRACP-0067490, was marked for 6 identification.) 7 - - - 8 THE WITNESS: Go ahead. 9 BY MR. HAVERTY: 10 Q. This is an email from Benjamin 11 Grover to you, among other people. Correct? 12 A. Yes. 13 Q. Dated June 8, 2013. And it looks 14 to me, and correct me if I'm wrong, that there 15 was a theory that was tested about whether if you 16 flipped the membrane so that the PTFE, the 17 hydrophobic section of the PTFE, was on the 18 inside of the cap, whether you could still -- 19 whether it would remain gas permeable even if it 20 got wet. Correct? 21 A. Correct. 22 Q. That was a theory that was 23 tested. Right? 24 A. Yes, that is correct.</p>	<p style="text-align: right;">Page 128</p> <p>1 A. Correct. Because these steps can 2 happen in -- in parallel. That's why. 3 Q. Okay. But you would -- you 4 would -- you would have to complete your design 5 review of the new material before you would send 6 out for validation, wouldn't you? 7 A. Not necessary. 8 Q. Why not? 9 A. Design review is not required to 10 initiate a validation. Design -- design review 11 is required to release something new into 12 production. 13 Q. And for the purposes of 14 validation could be one of those reasons for 15 releasing it into production. Right? 16 A. I'm sorry. I'm not clear on the 17 question. Can you ask again, please? 18 Q. I'm sorry. I'm not an engineer, 19 so I'm trying to wrap my head around this 20 process. 21 A. That's -- that's fine. 22 Q. You identify alternative 23 materials in October of 2013. That's your goal. 24 And then you develop the material. And then you</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. And I take it from this email 2 from Mr. Grover that that didn't work either. 3 Right? 4 A. That is correct. It didn't. 5 Q. So that was -- that was a 6 solution that was basically tested and rejected. 7 Correct? 8 A. Correct. 9 Q. Okay. Going back to Exhibit 2, 10 again, on the "Action Plan." 11 And you've got number 3 is 12 "Design Review" is due 4/21/2014. Right? 13 A. Yes. 14 Q. What is the design -- what is the 15 design review process? 16 A. Design review is a -- is a 17 procedural process as part of the Medtronics 18 quality system where whenever the change is being 19 introduced, it needs to be reviewed and agreed 20 upon by a multifunctional team before proceeding 21 and needs to be documented as such. 22 Q. So that, even though it's step 3, 23 it actually was due a month before the validation 24 with the new material. Correct?</p>	<p style="text-align: right;">Page 129</p> <p>1 want to validate it by actually manufacturing it 2 in a process. Correct? And make sure that it 3 meets the specifications that it's designed for. 4 Right? 5 A. Correct, yes. 6 Q. But you actually have to design 7 it before you can create the material, and then 8 create a process to validate it. Right? 9 A. That is correct. 10 Q. And that's what I'm trying to 11 understand is wouldn't -- wouldn't you be 12 reviewing the design of it before you actually 13 tried to put the material into process through 14 validation? 15 A. So again, there are different 16 ways to approach this. At this particular case, 17 we took a risk and asked supplier to start 18 validating once we've identified the material. 19 And then we did the design review as a formal 20 conclusion, if you will, for this -- and again, 21 this was not a final design review. This was the 22 final -- this was design review aimed to review 23 the design intent, not to -- not to release the 24 material to production.</p>

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<p style="text-align: right;">Page 130</p> <p>1 Q. And we're going to get into this 2 in a little bit more detail shortly, but when you 3 talked about you took a risk with a manufacturer, 4 you meant you had actually done some testing on a 5 number of materials, about five different 6 materials. Correct?</p> <p>7 A. We started with five and then we 8 reduced it to three and further reduced it to 9 two, yes.</p> <p>10 Q. And that was based upon the 11 characteristics of how well they would allow air 12 to flow when wet. Correct?</p> <p>13 A. That and also how -- how well 14 they behave in a high-volume manufacturing 15 environment, considering the machinery we use.</p> <p>16 Q. Right. I think some of them you 17 found that they were too fragile. Even if they 18 were good at remaining gas permeable, they were 19 too fragile to actually undergo the manufacturing 20 process. Right?</p> <p>21 A. That's correct.</p> <p>22 Q. But anyway, if we go back to the 23 "Action Plan," you had step 4 to "Qualify New 24 Material on the Product Level -- Due:</p>	<p style="text-align: right;">Page 132</p> <p>1 A. And then he infusion set tested 2 as a part of the system to -- to validate the 3 changes.</p> <p>4 Q. Got it. So that would be the 5 complete assembly process at that point. 6 Correct?</p> <p>7 A. Correct, correct.</p> <p>8 Q. So by that time you would have -- 9 you hoped to validate the assembly of the P-cap 10 with the new membrane material by itself and then 11 did the further step of assembling the entire 12 product. Right?</p> <p>13 A. That's correct.</p> <p>14 Q. Would there be a separate 15 validation for that process, or was that just the 16 qualifying it on the product level?</p> <p>17 A. In this particular case -- and, 18 again, I don't remember how exactly we executed 19 that, but in this particular case, it did not 20 require a full validation of the process, just 21 to -- how it affected the process with the 22 change.</p> <p>23 Q. Because you had -- it identifies 24 it in step 2 that you've got a highly customized,</p>
<p style="text-align: right;">Page 131</p> <p>1 4/28/2015."</p> <p>2 So that would be a year after you 3 validated the assembly process. Right?</p> <p>4 A. Right.</p> <p>5 Q. Meaning when you're qualifying 6 the new material on the product level, you 7 validated it, you know that you can manufacture 8 it to the specifications, and then you need to 9 know whether or not you can do it on a large 10 manufacturing level. Correct?</p> <p>11 A. Not exactly like that.</p> <p>12 So step 2 in the plan and step 4 13 are two different -- distinctly different 14 manufacturing processes. Step 2 refers to what 15 we call the P-cap assembly --</p> <p>16 Q. Okay.</p> <p>17 A. -- where a plastic P-cap housing 18 is populated, if you will, with the membrane and 19 the needle. That's one manufacturing process. 20 It needs to be validated separately.</p> <p>21 And the product level validation 22 is where the assembled P cap, or P cap assembly, 23 is assembled onto an infusion set.</p> <p>24 Q. Okay.</p>	<p style="text-align: right;">Page 133</p> <p>1 fully automatic machine for assembling these 2 P-caps. Correct?</p> <p>3 A. Correct.</p> <p>4 Q. So you wanted to make sure that 5 you didn't impact the equipment that's already in 6 place and have to redesign that or retool it to 7 deal with the new material. Correct?</p> <p>8 A. Absolutely. Yes.</p> <p>9 Q. What you needed to do is make 10 sure that you had a material that would fit 11 within the already-existing manufacturing 12 process. Right?</p> <p>13 A. Correct. At this point, that was 14 the case.</p> <p>15 Q. Okay. If you could take a look 16 at -- strike that.</p> <p>17 Before we go there, and then step 18 5 was "Regulatory Submission," and that was 19 estimated at that time to be submitted on or 20 about July 17th of 2015. Correct?</p> <p>21 A. Correct.</p> <p>22 Q. So you were anticipating at this 23 point that -- about a two-year process between 24 identifying the problem and alternative materials</p>

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<p style="text-align: right;">Page 134</p> <p>1 and getting FDA approval. Correct?</p> <p>2 A. Correct.</p> <p>3 Q. And what was the basis or where</p> <p>4 did you derive that date of July 17, 2015 as your</p> <p>5 expected date for submission to regulatory?</p> <p>6 A. Based on the completion -- on</p> <p>7 estimated completion of the previous steps,</p> <p>8 validation and validation testing and</p> <p>9 verification testing and so on and so forth.</p> <p>10 Q. And what you have here, this</p> <p>11 action plan, is that part of your responsibility</p> <p>12 as the CAPA leader at this point to come up with</p> <p>13 these dates?</p> <p>14 A. That is correct.</p> <p>15 Q. And are these dates submitted to</p> <p>16 the CAPA board so that they become like deadlines</p> <p>17 for you to -- for them to evaluate how well the</p> <p>18 CAPA is moving along?</p> <p>19 A. That is correct, yes.</p> <p>20 Q. And you mentioned before that</p> <p>21 from time to time you may have requested</p> <p>22 extensions of these dates.</p> <p>23 Would that have to go to the CAPA</p> <p>24 board for approval?</p>	<p style="text-align: right;">Page 136</p> <p>1 is Sandra Perez?</p> <p>2 A. Sandra Perez is a CAPA</p> <p>3 coordinator or CAPA analyst at Medtronic.</p> <p>4 Q. Okay. What is the job of a CAPA</p> <p>5 analyst?</p> <p>6 A. To help us to make sure that</p> <p>7 CAPAs stay on track and help us with the</p> <p>8 reporting software, which is very complicated.</p> <p>9 Q. And there was another person I</p> <p>10 wanted to ask you about, let me see if I can find</p> <p>11 this, Andreasen, what's his first name?</p> <p>12 A. Andy.</p> <p>13 Q. Andy Andreasen. Who was Andy</p> <p>14 Andreasen?</p> <p>15 A. Andy Andreasen was a quality</p> <p>16 manager back at the time.</p> <p>17 Q. Okay. What was his role, if any,</p> <p>18 in this CAPA?</p> <p>19 A. I think he was one of the initial</p> <p>20 approvers on the CAPA tasks.</p> <p>21 Q. Okay.</p> <p>22 A. Reviewer/approvers, if you will.</p> <p>23 Q. Meaning what we were just talking</p> <p>24 about, the action plan? Would he be one of the</p>
<p style="text-align: right;">Page 135</p> <p>1 A. I think -- there are different</p> <p>2 ways of extension approval process. And each</p> <p>3 subsequent extension requires more strict review</p> <p>4 and approvals, if you will, than the previous</p> <p>5 one.</p> <p>6 Q. Okay. So whenever you make your</p> <p>7 initial dates, you want to make sure that you</p> <p>8 have the maximum amount of leeway in order if an</p> <p>9 extension is going to be needed, because you're</p> <p>10 going to have to have increasingly significant</p> <p>11 justifications for an extension. Right?</p> <p>12 MR. MERRELL: Objection to form.</p> <p>13 MS. MARTINEZ: Objection to form.</p> <p>14 THE WITNESS: When I create --</p> <p>15 this is, in essence, a project, and a</p> <p>16 CAPA leader is a project manager. A job</p> <p>17 of a project manager is to estimate to</p> <p>18 the best of abilities and knowledge the</p> <p>19 durations of the test in the project, and</p> <p>20 this is exactly what I attempted on this</p> <p>21 one.</p> <p>22 BY MR. HAVERTY:</p> <p>23 Q. By the way, I meant to ask you</p> <p>24 this, and I should have asked it a while ago, who</p>	<p style="text-align: right;">Page 137</p> <p>1 approvers on that, do you know?</p> <p>2 A. Andy Andreasen left the company</p> <p>3 while this CAPA was in process, so I don't</p> <p>4 remember if he approved the action plan or it was</p> <p>5 somebody else.</p> <p>6 Q. Okay. I just saw his name on the</p> <p>7 documents earlier and wanted to know who he was.</p> <p>8 A. Yeah.</p> <p>9 Q. Who else were approvers on this</p> <p>10 CAPA plan?</p> <p>11 A. They changed during the course of</p> <p>12 the CAPA, but various quality managers and</p> <p>13 functional managers and independent reviewers.</p> <p>14 Q. Was there any person in</p> <p>15 particular who you would have reported to during</p> <p>16 the course of this CAPA?</p> <p>17 A. Are you referring as the one</p> <p>18 over -- as a manager to me or --</p> <p>19 Q. Yes, yes.</p> <p>20 A. Well, I have my functional</p> <p>21 manager, and I also reported this to CAPA</p> <p>22 reviews, periodic CAPA reviews, and sometimes</p> <p>23 even -- even our CEO does a CAPA review.</p> <p>24 Q. Your CEO, I'm sorry, did you say?</p>

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<p style="text-align: right;">Page 138</p> <p>1 A. Yes. 2 Q. Okay. 3 A. Yes. 4 Q. Do you know whether the CEO is -- 5 this is of Medtronic Diabetes or MiniMed? 6 A. Correct. 7 Q. Do you know whether the CEO of 8 MiniMed ever reviewed this CAPA? 9 A. Yes. I know that he has. He 10 had. 11 Q. Okay. Do you know on more than 12 one occasion? 13 A. On an occasion -- on an occasion 14 that there is such thing that is called aging 15 CAPA, there are -- that have been open for longer 16 than anticipated, let's put it this way. Yeah. 17 Q. Okay. And what's the purpose of 18 the CEO reviewing an aging CAPA? 19 A. Because CAPA is a big part of 20 reporting to regulatory bodies, and that's 21 important that they stay on time. And they 22 progress and then they close eventually. 23 Q. And are you aware of the fact 24 that the FDA, even in a warning letter that</p>	<p style="text-align: right;">Page 140</p> <p>1 through MDT-BRACP-0067256, was marked for 2 identification.) 3 - - - 4 BY MR. HAVERTY: 5 Q. Do you have that? 6 A. I do. 7 Q. This is another PowerPoint slight 8 deck titled "Prime/Fill Anomaly Review" dated 9 April 24, 2013. 10 Have you ever seen this slide 11 deck before? 12 A. Give me a second, please. 13 Q. Sure. 14 A. I recognize portions of it. I 15 cannot say exactly if I've seen this in its 16 entirety together in this -- in one presentation. 17 Q. Okay. Let me ask the question 18 this way: During the course of this CAPA, did 19 you ever prepare any PowerPoint presentations 20 that you presented? 21 A. Yes, I did. 22 Q. How many did you prepare? 23 A. I can't -- I don't remember. 24 Q. All right if you had done a</p>
<p style="text-align: right;">Page 139</p> <p>1 they've issued to Medtronic, talked about CAPAs 2 that were open for too long and never closed or 3 not closed properly? Do you recall that? 4 MR. MERRELL: Objection to form. 5 THE WITNESS: I'm not familiar 6 with the content on the -- of the warning 7 letter.</p> <p>8 BY MR. HAVERTY:</p> <p>9 Q. Okay. Were you aware that there 10 was a warning letter that was issued in 2013, 11 September of 2013?</p> <p>12 A. I am aware of that, yes.</p> <p>13 Q. Were you involved at all in the 14 responses to that warning letter to the FDA?</p> <p>15 A. No, I was not.</p> <p>16 Q. Did you ever review that warning 17 letter?</p> <p>18 A. No, I didn't.</p> <p>19 Q. If you could look at Exhibit 10, 20 please.</p> <p>21 - - -</p> <p>22 (Deposition Exhibit No. AA-10, 23 PowerPoint, "Prime/Fill Anomaly Review 24 4-24-13," Bates stamped MDT-BRACP-0069182</p>	<p style="text-align: right;">Page 141</p> <p>1 PowerPoint presentation and you prepared it, did 2 you typically put your name on it? 3 A. I would, yes. 4 Q. All right. Well, as of April 5 24th of 2013, would you have been involved with 6 this prime/fill anomaly review at that point, do 7 you know? 8 A. Again, I don't remember exactly 9 when I was assigned to this. 10 Q. Okay. We know that the CAPA was 11 opened on April 30th of 2013. 12 So you don't remember whether you 13 had any involvement prior to the opening of the 14 CAPA or not? 15 A. And even after opening the CAPA. 16 I don't remember if I was on the CAPA right from 17 the beginning. 18 Q. Okay. Well, in any event, if you 19 look at page 2 of that, it has a slide that's 20 called "Process Flow." 21 A. Yes. 22 Q. First of all, do you know what 23 that's referring to? 24 A. This particular refers to some</p>

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<p style="text-align: right;">Page 142</p> <p>1 process, that -- the steps of the process and 2 sequence of those.</p> <p>3 Q. So the first one is, it's "Event 4 Notification."</p> <p>5 I assume that refers to -- or 6 correct me if I'm wrong, that refers to the first 7 complaint about this phenomenon. Right? That's 8 how Medtronic was notified?</p> <p>9 A. It looks like this. I wouldn't 10 like to assume. This looks like a process flow 11 for a CAPA creation and CAPA reporting.</p> <p>12 Q. Right. And so step 2, it looks 13 like "Obtain product from Customer." We talked 14 about that, where there were some returned 15 infusion sets. Right?</p> <p>16 A. Right.</p> <p>17 Q. And then the third step, 18 "Standard Failure Analysis and/or Engineering 19 Study."</p> <p>20 We talked about that, there was 21 an engineering study, they identified what the 22 issue was. Right?</p> <p>23 A. Uh-huh, yes.</p> <p>24 Q. And then the next step is</p>	<p style="text-align: right;">Page 144</p> <p>1 A. Correct. 2 Q. All right. And then the next 3 step after the submission to the CAPA decision -- 4 And by the way, the QIT board is 5 the quality improvement team board?</p> <p>6 A. Correct. 7 Q. Is that the same thing as what 8 we've been referring to as the CAPA board?</p> <p>9 A. No, it's not. 10 Q. Okay. So that's a separate board 11 then. Right?</p> <p>12 A. Correct, yes. 13 Q. So do these decisions about 14 whether to open a CAPA go to both the CAPA board 15 and the QIT board?</p> <p>16 A. I don't exactly know how the 17 process works. 18 Q. Okay. 19 A. The QIT is the first line of 20 defense, if you will, and then CAPA board. 21 Q. Got it. 22 So if it goes to the CAPA board, 23 that means it's already gone through the QIT 24 board?</p>
<p style="text-align: right;">Page 143</p> <p>1 "Confirm Failure/Understand 2 Implications/Understand Root Cause." 3 We -- that was identified as 4 well. Correct?</p> <p>5 A. Correct.</p> <p>6 Q. And then it has "Risk Analysis 7 and/or...(Health Hazard Evaluation)." 8 That -- was that done by the time 9 you got involved in the CAPA, do you know?</p> <p>10 A. It was, yes.</p> <p>11 Q. Okay. And then the next step is 12 "CAPA decision -- QIT board." 13 So from what you said -- told us 14 a little bit earlier, all of these steps 15 ultimately led to a decision because of the 16 information that was gained from it to submit 17 this issue to a CAPA board to see whether a CAPA 18 was appropriate to be opened. Correct?</p> <p>19 A. Correct.</p> <p>20 Q. And because you got involved in 21 it ultimately, and we saw from the Exhibit 2, a 22 CAPA -- a decision was made that the situation 23 was significant enough to warrant a CAPA. 24 Correct?</p>	<p style="text-align: right;">Page 145</p> <p>1 A. Yes. That's -- it does. 2 Q. And that means that the QIT board 3 felt that the situation merited a decision about 4 whether to open a CAPA. Right?</p> <p>5 A. Right. QIT board made a decision 6 that there is an anomaly that's worth looking 7 into in that aspect.</p> <p>8 Q. The next step is field 9 correction -- "Field Corrective Action 10 Decision -- Quality Assurance plus Regulatory 11 Affairs plus QIT Board." Correct?</p> <p>12 A. Yes. 13 Q. And a field corrective action is 14 something like a "dear healthcare provider" 15 letter? That's one thing?</p> <p>16 A. One of the things. Can be a 17 number of things. 18 Q. What else could constitute a 19 field corrective action?</p> <p>20 A. It could be a recall. It could 21 be -- it could be a product hold. It could be a 22 seizing of shipments. Many different things. 23 Q. Okay. All right. Then the next 24 step was to create a "Field Corrective Action</p>

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1 Plan." 2 And I guess -- I'm assuming that 3 was assigned to regulatory affairs, do you know? 4 A. From this process flow, it looks 5 like that. 6 Q. By the way, over to the right 7 there, it says vice president -- right between 8 confirming and understanding the root cause and 9 the risk analysis and HHE, there's a step to the 10 right that says, "VP Quality Assurance to inform 11 Corporate ASAP on potential field corrective 12 action items." 13 Do you see that? 14 A. I do. 15 Q. Do you know what that's referring 16 to? 17 A. Referring to corporate 18 communication means? 19 Q. Yeah. Do you know why the VP of 20 quality assurance was to inform corporate as soon 21 as possible on potential field corrective action 22 items? 23 A. No, I don't know why. 24 Q. And by the way, in referring to	Page 146 1 headquarters. Right? 2 A. Correct. 3 Q. All right. Let's skip ahead a 4 number of pages, because a lot of this is 5 redundant of an earlier one. 6 So if you could go to the page, 7 the last three numbers are 192 down at the bottom 8 right. 9 A. Which page, I'm sorry? 10 MS. MARTINEZ: 192. 11 THE WITNESS: I'm getting there. 12 BY MR. HAVERTY: 13 Q. It says "Next Steps." 14 A. One second, please. 15 Uh-huh, yes. 16 Q. Okay. And the next page after 17 that is captioned "P-cap wet flow spec 18 development." 19 Do you see that? 20 A. Yes. 21 Q. Could you tell us what that 22 refers to? 23 A. This refers to development of a 24 specification for the P-cap assembly that will
Page 147 1 corporate, are they referring to corporate at 2 MiniMed or corporate in Minneapolis? 3 A. Can't answer that question from 4 here. 5 Q. When they use the shorthand 6 corporate, do you know what they're referring to? 7 A. Corporate usually is referred to 8 Minneapolis. 9 Q. Okay. 10 A. To Medtronic corporate. 11 Q. All right. Okay. And then the 12 last step in the process flow was "Approve Plan." 13 And that was assigned to the vice president of 14 quality assurance, general manager of diabetes 15 and SVP international, vice president quality 16 assurance corporate. 17 What is SVP international -- 18 A. Senior vice president. 19 Q. -- do you know? 20 Okay. Of international. And 21 then vice president of quality assurance at 22 corporate. 23 And you said you believe that 24 refers typically to Minneapolis, Medtronic	Page 149 1 govern, if you will, how much fluid -- to 2 determine how much fluid can be deposited inside 3 the P-cap while remaining functionality of the 4 P-cap or the P-cap vent. 5 Q. Just -- 6 A. The maximum amount of fluid 7 allowed -- safely allowed that -- at which the 8 P-cap membrane or P-cap venting properties will 9 function as designed. 10 Q. Right. And so you actually did a 11 study with people, did you not, that examined 12 them misfilling the reservoirs and determining 13 how much on average was deposited, the insulin. 14 Correct? 15 A. That is correct. We did a study 16 with 60 people who were given knowingly incorrect 17 instructions on how to fill the reservoir, and 18 then whenever spillage would occur, we would 19 measure how much was spilled. 20 Q. And if you look to the next page, 21 it's a slide that says, "How wet does the 22 membrane get?" 23 Do you see that? 24 A. Yes.

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1 Q. And this dot plot, is this 2 derived from the data from the study that you did 3 with people who deliberately improperly filled 4 the reservoirs? 5 A. Yes. Correct. 6 Q. And from that, you were trying to 7 determine in actual practice what you might 8 expect in terms of if someone makes this mistake, 9 how much -- what's the maximum amount of insulin 10 that could get spilled onto the reservoir and 11 then contaminate the membrane. Right? 12 A. Correct. 13 Q. And from that, then you -- your 14 goal was to develop a membrane material that 15 could remain gas permeable even if the maximum 16 amount of insulin was deposited on the reservoir 17 and then contaminated the membrane. Correct? 18 A. Yes, but these studies were kind 19 of independent. 20 Q. Well, but you needed some data 21 points. Right? You needed to develop -- because 22 the next thing that you developed was the wet 23 flow specification. Correct? 24 A. Correct. So -- but it has not --	Page 150 1 What does the data mean just generally? 2 A. The first thing it tells us, that 3 the membrane that was in production at that time 4 gets saturated very quickly with very little and 5 stops being permeable, and it also tells us that 6 three materials -- at this point, we were down to 7 three materials selected for further testing, 8 that any of those three can fulfill the design 9 requirement. 10 Q. And what was the -- meaning what, 11 that it would still allow air to flow even when 12 wet at -- maximally? 13 A. To -- to a certain point. 14 Q. Okay. 15 A. There is no membrane out there 16 that can continue flow with -- with an infinite 17 amount of fluid deposited. 18 Q. Right. And looking over to the 19 right on the legend there, on this chart, it has 20 the current membrane, then it has PM22S, Supor 21 450R and Versapor 450R. Right? 22 A. Correct. 23 Q. Okay. And there's three -- those 24 other three, PMS -- PM22S, the Supor 450R, and
Page 151 1 it had nothing to do with the material selection. 2 We needed to determine how much -- how much fluid 3 can be produced during the incorrect -- incorrect 4 filling of the reservoir and whether -- then 5 whether our material can withstand that or not. 6 Q. Right. I thought that's what 7 I -- maybe I said it incorrectly. 8 But the idea was you were 9 collecting -- you needed to have a baseline of 10 data for how much contamination are we talking 11 about in the first place. Right? 12 A. Correct. 13 Q. Okay. And then if you go to the 14 next slide -- and then we're going to break 15 here -- but "Wet Flow vs. Applied Insulin," what 16 does that mean? What's that referring to? 17 A. That means that there was a study 18 done on I believe four materials at this point to 19 determine -- to determine the correlation of a 20 flow versus amount of, in this case, insulin 21 deposited onto the membrane. 22 Q. Okay. And it's impossible to 23 read that scatter plot. 24 But what does that tell you?	Page 153 1 the Versapor 450R, were the three remaining 2 candidates of the original five that you 3 developed. Correct? 4 A. Correct. 5 Q. And you may have told me, but I 6 forgot, what was the reason that two of them were 7 eliminated initially? 8 A. Due to the -- due to their 9 physical -- physical properties, they were too 10 brittle and too thin to handle in the machine 11 environment. 12 Q. Okay. The PM22S, who is the 13 manufacturer of that? 14 A. Porex. 15 Q. And the Supor 450R, who is the 16 manufacturer of that? 17 A. Pall Corporation. 18 Q. P-A-L-L? 19 A. P-A-L-L. 20 Q. Okay. And the Versapor 450R, who 21 is the manufacturer of that? 22 A. That is made by Pall as well. 23 Q. All right. 24 COURT REPORTER: Excuse me, by

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<p style="text-align: center;">Page 154</p> <p>1 who? 2 MR. HAVERTY: Pall, Pall as well. 3 BY MR. HAVERTY: 4 Q. And how did you get to these 5 suppliers of these materials? How did you select 6 them? 7 A. So Ben Grover, who was a -- an 8 engineer assigned to the project, he reached out, 9 so, naturally, first to Pall Corporation, who is 10 the manufacturer of the original membrane, if we 11 can refer to that, the membrane that was used in 12 the P-cap prior to change. 13 Q. That was -- 14 A. And -- 15 Q. Before you go there, that was the 16 Emflon material. Right? 17 A. I think it called Emflon, yes. 18 MR. HAVERTY: E-M-F-L-O-N. 19 BY MR. HAVERTY: 20 Q. Yes. Okay. 21 A. It was only natural to reach out 22 to a current supplier to seek help on this. And 23 so two materials came from them. 24 And he also, through this</p>	<p style="text-align: center;">Page 156</p> <p>1 Q. -- if you look to the legend, it 2 has the various materials. And then in 3 parentheses it has numbers, 0.21/100, 0.20 -- 4 what is that referring to? Is that a 5 quantitative analysis? 6 A. That's quantitative analysis and 7 probably some projections, mathematical 8 projections as to how many units will get 9 blocked -- how many units of a sampled -- sample 10 size of 100 will get blocked -- 11 Q. Right. 12 A. -- when certain amount of fluid 13 is introduced to them. 14 Q. Got it. So the PM22S was .21 out 15 of 100 or 0.21 out of 100. The Supor was about 16 the same, 0.20 out of 100. And the Versapor 450R 17 was 0.14 out of 100. Right? 18 A. Correct. 19 Q. That was compared to the current 20 Emflon membrane, which is 5.35 out of 100. 21 Correct? 22 A. Correct. 23 Q. So that number is way in excess 24 of the numbers for the other three materials.</p>
<p style="text-align: center;">Page 155</p> <p>1 research, found this company named Porex that 2 specializes in filtration and membrane 3 manufacturing. 4 Q. Okay. And if you go to the next 5 page -- oh, I'm sorry. I interrupted you, and I 6 meant to follow up. 7 The Versapor, how did you -- how 8 did you get to them? 9 A. Both Versapor and Supor came from 10 Pall Corporation, who were the supplier at the 11 time. 12 Q. Okay. And then how did you get 13 to Porex then? 14 A. Ben found them through his 15 engineering research. I'm not sure how. 16 Q. Then the next page has "Blockages 17 per 100 spills." 18 What's that referring to? 19 A. Okay. These I don't remember 20 exactly. These are -- and it's hard to judge 21 what these are from black-and-white graphs. 22 Q. Yeah, I know. 23 But if you look -- 24 A. Yeah.</p>	<p style="text-align: center;">Page 157</p> <p>1 Correct? 2 A. Correct. 3 Q. And then if you go to the next 4 page, it looks like it's essentially just a 5 different version of the same data. Right? 6 A. Different -- different 7 presentation of the same data, yeah. 8 Q. And then if you go to the next 9 page, it has "Estimated Blockages per Million 10 Spills." 11 Do you see that? 12 And it looks like it has ranges. 13 Right? 14 A. Correct. 15 Q. So for the PM22S, the low was 16 2,132, and the high was 5,289. 17 The Supor was 2,020 for a low and 18 5,184 for a high. 19 And the Versapor 450R was 1,395 20 for a low and 4,425 for a high, as compared to 21 the Emflon membrane, the current membrane, which 22 was a low of 53,490 and a high of 63,227. 23 Correct? 24 A. Correct.</p>

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<p style="text-align: right;">Page 158</p> <p>1 Q. So that's also, again, vastly in 2 excess of the other three materials. Right? 3 A. That is correct. 4 Q. If you go to the next page real 5 quickly, it says, "No Effect on FMEA." That's 6 failure modes and effects analysis. Correct? 7 A. Yes. 8 Q. What is that referring to, are 9 you able to tell? 10 A. Failure mode and effect analysis 11 is an analytic tool that allows us to -- to 12 predict and judge the potential risk of a certain 13 failure. 14 Q. Right. 15 A. And also the occurrence and how 16 well that potential failure can be detected and 17 prevented. 18 Q. Right. And if you go to the 19 bottom there, it's got the arrows talking about 20 the vent membrane being blocked. Right? 21 And it says, the "Current Design 22 Controls" for that is "Patient training" and 23 "instructions for use." Correct? 24 A. Correct.</p>	<p style="text-align: right;">Page 160</p> <p>1 candidate to reduce the risk of the blocked 2 membrane? 3 MR. MERRELL: Objection -- 4 objection to form. 5 THE WITNESS: At that point, yes. 6 BY MR. HAVERTY: 7 Q. Okay. And it talks about the wet 8 flow spec. Again, we're going back to this. 9 Was that something -- we're going 10 to talk about this after the break. 11 Is that something that you 12 ultimately developed, because you said there is 13 no known membrane cable of eliminating the risk, 14 but you develop a spec that says that the -- must 15 be gas permeable at a certain level depending 16 upon an exposure to the contaminant -- 17 A. Correct. 18 Q. -- that was what the wet flow 19 spec was? 20 MR. HAVERTY: All right. Why 21 don't we take a break here, and then we 22 can pick up, and we'll talk about the 23 development of the wet flow spec after 24 the break. All right?</p>
<p style="text-align: right;">Page 159</p> <p>1 Q. So what is this referring to? 2 How does it -- when it says it has no effect on 3 failure modes and effect analysis, what does that 4 mean? 5 A. Because the introduction of a new 6 membrane does not change the potential failure or 7 potential for a failure. It may reduce the 8 occurrence, but it does not completely prevent it 9 from happening. So again, this is an analytical 10 tool that assesses the potential of a failure and 11 that stays present. 12 Q. And lastly, if you go to the next 13 page, it says, "Based on current data Versapor 14 450R provides the greatest risk reduction for our 15 customers." 16 Next bullet point, "No known 17 membrane is capable of eliminating the risk." 18 Three, "We need to find a way to 19 monitor the level of protection provided by the 20 membrane going forward (wet flow spec)?" 21 Do you see that? 22 A. I do. 23 Q. Is that your recollection in the 24 course of this CAPA about Versapor being the best</p>	<p style="text-align: right;">Page 161</p> <p>1 MR. MERRELL: Okay. 2 MR. HAVERTY: Great. 3 THE VIDEOGRAPHER: We are now 4 going off the record, and the time is 5 12:57 p.m. 6 - - - 7 (A luncheon recess was taken from 8 12:57 p.m. to 1:41 p.m.) 9 - - - 10 THE VIDEOGRAPHER: We are now 11 going back on the record, and the time is 12 1:41 p.m. 13 BY MR. HAVERTY: 14 Q. Mr. Aleksandrovich, could you 15 take a look at Exhibit 19, please. 16 - - - 17 (Deposition Exhibit No. AA-19, 18 Field Corrective Action Plan - Paradigm 19 Insulin Infusion Sets Potential for Fluid 20 to Block Tubing Connector Vent Membranes 21 DFCAP 2013-03 Rev 2 May 22, 2013, Bates 22 stamped MDT-BRACP-029780 through 23 MDT-BRACP-029809, was marked for 24 identification.)</p>

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1 - - - 2 MR. MERRELL: Corrective action 3 plan. Okay. 4 BY MR. HAVERTY: 5 Q. You have it? Okay. 6 That's the field corrective 7 action plan from May 22, 2013. 8 Do you see that? 9 A. Yes. 10 Q. Have you seen this field 11 corrective action plan before? 12 A. I have. 13 Q. And by the way, let me go back to 14 something I should have asked you way, way back 15 at the beginning of this deposition. 16 What documents, if any, did you 17 review in preparation for this deposition today? 18 A. So a copy of the CAPA report and 19 whatever the attachments were to that and -- 20 including this. 21 Q. Including the field -- 22 A. This -- 23 Q. -- the field corrective action? 24 A. The field corrective action	Page 162 1 less when the infusion set cannula is inserted 2 into a patients subcutaneous tissue, the results 3 of testing performed to date suggest there is a 4 potential for significant insulin over-delivery 5 if the tubing connector membranes are completely 6 blocked. Significant insulin over-delivery can 7 lead to death or serious injury if not treated 8 immediately." 9 And that was consistent with the 10 testing that was done and the root cause analysis 11 and everything. Correct? 12 A. Correct. 13 Q. Okay. And by the way, were you 14 consulted at all about this field corrective 15 action? 16 A. No. In what aspect? 17 Q. In any aspect. Were you asked to 18 offer any insights? Did you review it before it 19 became final or -- 20 A. No. 21 Q. All right. 22 A. No, I was not. 23 Q. The next paragraph goes -- says 24 that "In addition there is also a risk of
Page 163 1 report. And that's pretty much it. 2 Q. And when you said you reviewed 3 the CAPA report, did you review the CAPA report 4 that we've identified as Exhibit 2? 5 A. That is correct. 6 Q. That is the one that was -- 7 that's the -- the last one, the one that was 8 closed and should contain all of the synthesized 9 information. Right? 10 A. Correct. 11 Q. Anyway, if you could turn to 12 page -- it's the page at the bottom that's 13 marked 29 -- the last three numbers are 784. 14 A. Okay. 15 Q. In the upper third of the field 16 corrective action, it notes a potential health 17 hazard relating to this blocked vent. It says, 18 "The most significant hazard associated with 19 tubing connector vent blocking is the potential 20 for insulin over-delivery. This behavior could 21 also result in temporary under-delivery of 22 insulin. 23 "Although it is not clear whether 24 or not the amount of insulin delivered will be	Page 165 1 significant insulin under-delivery associated 2 with blocked tubing connector vents. Preliminary 3 testing suggests that if the infusion set is 4 inserted after insulin stops flowing in 5 situations where the tubing connector vents are 6 blocked, insulin delivery will not resume 7 immediately." 8 That's what we talked about 9 earlier where there is a gap between the slide 10 screw and the reservoir stopper. Correct? 11 A. Correct. 12 Q. Okay. And then underneath that, 13 it says, "Distribution Information. As of the 14 end of March 2013 a total of 428,000 current 15 Paradigm insulin infusion pump users are 16 registered in our database." 17 So that -- those would be the 18 users actually, presumed users. Correct? 19 A. Correct. 20 Q. And then it notes the proposed 21 field correction plan was to send communications 22 "to inform patients to dry any spilled fluid that 23 may come into contact with the inside of the 24 tubing connector." So they were going to send

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<p style="text-align: center;">Page 166</p> <p>1 out a customer letter, a healthcare professional 2 letter, a distributor letter, a wholesale letter 3 and "In addition to the communications provided 4 to existing Paradigm pump users, a package 5 insert...is being included with shipments of 6 Paradigm insulin...reservoirs and Paradigm" 7 insulin "infusion sets." 8 Do you see that? 9 A. I do. 10 Q. And do you know what the package 11 insert was that was attached to it? 12 A. No. I do not recall this. This 13 package insert is utilized in our warehouse in 14 Kentucky, and I don't think I've ever seen that 15 insert. 16 Q. Okay. And by the way, am I 17 correct, to short-circuit this a little bit, but 18 ultimately the FDA characterized this corrective 19 action as a Class 1 recall, did it not? 20 A. That is correct. 21 Q. And the reason for that was 22 because of the severity of the risk. Correct? 23 A. I can't speak to FDA's reasons. 24 Q. But you know that they</p>	<p style="text-align: center;">Page 168</p> <p>1 of, as we talked about a little bit earlier, a 2 form of warning to the patients to instruct them 3 how to avoid getting the insulin spilled on the 4 reservoir top. Correct? 5 A. Yes. Correct. 6 Q. So this was one of the corrective 7 actions in the corrective and preventative action 8 program. Correct? 9 MR. MERRELL: Objection to form. 10 THE WITNESS: Again, I wouldn't 11 bucketize these actions that we take as 12 part of CAPA to -- into corrective and 13 preventative. This -- the entire goal of 14 the CAPA is to provide a solution to keep 15 the patient safe. 16 BY MR. HAVERTY: 17 Q. Right. But this was a -- this 18 was a near-term solution, because you didn't know 19 how long it was going to take or if you even 20 could design out the hazard that you had 21 identified. Correct? 22 A. That is -- 23 MR. MERRELL: Objection to form. 24 THE WITNESS: That is correct.</p>
<p style="text-align: center;">Page 167</p> <p>1 specifically identified it as a Class 1 recall. 2 Right? 3 A. That I do, yes. 4 Q. Okay. And if you turn to the 5 page numbered 793. This is patient -- 6 A. Go ahead. 7 Q. This is an "Urgent Medical Device 8 Safety Notification" relating to the "Potential 9 for Over or Under Delivery of Insulin if Insulin 10 or Other Fluids Contact the Inside of Medtronic 11 Paradigm Infusion Set Connectors." 12 Do you see that? 13 A. Yes. 14 Q. This was the letter that was sent 15 to patients in early June of 2013, is it not? 16 A. I'm not sure when it was sent to 17 patients, but yes, it is a letter that was sent 18 to patients. 19 Q. And in it here, there's a 20 pictograph with some text that shows how to 21 properly disconnect the reservoir -- the 22 reservoir from the transfer guard. Correct? 23 A. Correct. 24 Q. And this was sent in the manner</p>	<p style="text-align: center;">Page 169</p> <p>1 It was an immediate solution, yes. 2 BY MR. HAVERTY: 3 Q. But I think you told us a little 4 bit earlier that the people who were involved in 5 the CAPA did not think it was a satisfactory 6 solution because of the possibility of the human 7 error leading to this over-delivery of insulin. 8 Correct? 9 MR. MERRELL: Objection to form. 10 THE WITNESS: That is correct. 11 We wanted to -- to ensure that we take 12 even the possibility of this thing 13 happening away from patient as much as we 14 can. 15 BY MR. HAVERTY: 16 Q. If you could go back to 17 Exhibit 10, please. 18 - - - 19 (A discussion off the record 20 occurred.) 21 - - - 22 BY MR. HAVERTY: 23 Q. Yeah, and I think -- and 24 actually, I will represent to you I think that</p>

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<p style="text-align: center;">Page 170</p> <p>1 these are -- were intended to be two separate 2 exhibits, but they got mashed together for some 3 reason. So the numbering may be a little bit 4 confusing.</p> <p>5 But, you know, let me ask you, if 6 you could go to the page marked 242. It's near 7 the back. It's about ten pages from the end or 8 so.</p> <p>9 A. 242.</p> <p>10 Q. 242?</p> <p>11 MS. MARTINEZ: NO.</p> <p>12 THE WITNESS: 0069242 (sic).</p> <p>13 Right?</p> <p>14 BY MR. HAVERTY:</p> <p>15 Q. Yeah. But I said, there are 16 actually two things together. The numbering is 17 not in sequence, so go all the way towards the 18 end first.</p> <p>19 MR. MERRELL: 0067242.</p> <p>20 MS. MARTINEZ: Oh.</p> <p>21 MR. HAVERTY: Yeah.</p> <p>22 THE WITNESS: 7247. I'm lost.</p> <p>23 MR. MERRELL: It's not in 24 sequence.</p>	<p style="text-align: center;">Page 172</p> <p>1 Q. Would you -- do you recall 2 whether you were involved in any type of 3 presentation in July of 2013 regarding the 4 Paradigm CAPA?</p> <p>5 A. July 2013 -- could you please ask 6 me that question again?</p> <p>7 Q. Sure. Let me make it a little 8 bit easier for you.</p> <p>9 A. Uh-huh.</p> <p>10 Q. Let me do it this way. 11 Hold that page open and go to 12 Exhibit 17, if you would.</p> <p>13 - - -</p> <p>14 (Deposition Exhibit No. AA-17, 15 Meeting Invitation, 6/3/2013, Bates 16 stamped MDT-BRACP-0054646, was marked for 17 identification.)</p> <p>18 - - -</p> <p>19 THE WITNESS: Okay.</p> <p>20 BY MR. HAVERTY:</p> <p>21 Q. Do you have that?</p> <p>22 A. Yes.</p> <p>23 Q. This is an email from Juan 24 Alderete to, among other people, you, Benjamin</p>
<p style="text-align: center;">Page 171</p> <p>1 THE WITNESS: Oh, there we go. 2 7242. Yes.</p> <p>3 BY MR. HAVERTY:</p> <p>4 Q. Got it. Okay. And it's a slide 5 deck called "Prime/Fill Anomaly - Paradigm CAPA"?</p> <p>6 A. Correct.</p> <p>7 Q. And it's from Juan Alderete?</p> <p>8 Yeah. It's dated July 5, 2013?</p> <p>9 A. Uh-huh.</p> <p>10 Q. Right?</p> <p>11 A. Yes. That's it.</p> <p>12 Q. Have you -- if you just take a 13 quick look at this, have you seen this slide deck 14 before?</p> <p>15 A. I don't remember exactly.</p> <p>16 Q. Who is Juan Alderete?</p> <p>17 A. He is an R&D engineer at 18 Medtronic.</p> <p>19 Q. Was he part of the CAPA team?</p> <p>20 A. No, he was not.</p> <p>21 Q. Do you know why he was giving a 22 presentation on the "Prime/Fill Anomaly - 23 Paradigm CAPA"?</p> <p>24 A. No, I don't remember exactly why.</p>	<p style="text-align: center;">Page 173</p> <p>1 Grover and Mark Curtis. 2 These are part of your CAPA team. 3 Correct?</p> <p>4 A. Some people are. Some are just 5 R&D people.</p> <p>6 Q. Yeah. No, no. But the ones that 7 I identified, Benjamin Grover, Mark Curtis, you, 8 they were all -- you were part of that CAPA team. 9 Right?</p> <p>10 A. Correct.</p> <p>11 Q. And I also note, there is another 12 person in there, Afshin Bazargan. 13 Who is Afshin Bazargan?</p> <p>14 A. He's an R&D director --</p> <p>15 Q. Okay. Is he still with 16 Medtronic?</p> <p>17 A. -- at Medtronic.</p> <p>18 Q. Is he still with Medtronic?</p> <p>19 A. He is.</p> <p>20 Q. Okay. Anyway, this -- it looks 21 like this was a meeting invitation for a meeting 22 for "Concept Generation for Venting Reservoir" 23 Component -- "Compartment" for June 3rd of 2013. 24 Do you recall going to such a</p>

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Page 174	Page 176
<p>1 meeting?</p> <p>2 A. Yes, I do.</p> <p>3 Q. Okay. What was the purpose of</p> <p>4 the meeting?</p> <p>5 A. To potentially generate a</p> <p>6 hardware solutions to prevent -- or to provide</p> <p>7 venting through the pump or some other means of</p> <p>8 venting the reservoir compartment.</p> <p>9 Q. Okay. All right. So if you go</p> <p>10 back to Exhibit 10, that page we were on, and you</p> <p>11 go to 243, which is the next page after that, it</p> <p>12 says, "Project Charter," and it has a "Problem</p> <p>13 Statement, The P-Cap membrane can become occluded</p> <p>14 and effect the pressure equalization of the</p> <p>15 System." That's identified as the "Issue</p> <p>16 Statement."</p> <p>17 Then it says, "Through Design,</p> <p>18 our tube based systems should equalize the</p> <p>19 reservoir compartment pressure under typical use</p> <p>20 conditions," and that's "Vision."</p> <p>21 And "We will use the DMAIC</p> <p>22 process to evaluate potential design solutions in</p> <p>23 order to reduce/mitigate the risk." And that's</p> <p>24 identified as the "Method."</p>	<p>1 A. I participated in a couple of</p> <p>2 meetings and, like I said, idea generations.</p> <p>3 Q. Okay. And then the "Project</p> <p>4 Scope" involves the Paradigm/NGP infusion sets</p> <p>5 and reservoirs, the 1.8 and 3.0 milliliter and</p> <p>6 the Paradigm/NGP pumps 5X -- 5 series and the 7</p> <p>7 series. Correct?</p> <p>8 A. Correct.</p> <p>9 Q. And, by the way, all of the stuff</p> <p>10 that we've been talking about, there are</p> <p>11 two models of pump back in this time. There was</p> <p>12 the 5 series and the 7 series. Correct?</p> <p>13 A. Correct.</p> <p>14 Q. The only difference between the 5</p> <p>15 series and the 7 series was the size of the</p> <p>16 reservoirs. Correct?</p> <p>17 A. Correct. And the size of the</p> <p>18 pump itself. Yeah.</p> <p>19 Q. But all of the issues that we're</p> <p>20 talking about with the blocked vents and all</p> <p>21 that, they apply equally to the 7 series as they</p> <p>22 do to the 5 series. Correct?</p> <p>23 A. Correct. It's pump independent.</p> <p>24 Yes.</p>
<p>1 Can you tell us what these things</p> <p>2 are, the Statement, the Vision and the Method,</p> <p>3 what does that refer to?</p> <p>4 A. This was a project -- conceptual</p> <p>5 project to try to generate some of the solutions</p> <p>6 via hardware to provide venting to the reservoir</p> <p>7 compartment.</p> <p>8 Q. Or -- or otherwise prevent the</p> <p>9 hazard from occurring. Right? Even it was not</p> <p>10 necessarily through venting. Right?</p> <p>11 A. Well, I wouldn't agree with that.</p> <p>12 It's all about venting. It's all about letting</p> <p>13 air out of the compartment.</p> <p>14 Q. Okay. We'll get to that in a</p> <p>15 second.</p> <p>16 Anyway, in any event, it notes</p> <p>17 that the "Project Goal" was to "Perform root</p> <p>18 cause analysis to determine failure modes and</p> <p>19 propose solutions to reduce/mitigate the</p> <p>20 failures." Right?</p> <p>21 A. Yes.</p> <p>22 Q. And do you recall -- you recall</p> <p>23 this project at all? Were you involved in this</p> <p>24 project?</p>	<p>1 Q. Okay. Anyway, if you go ahead to</p> <p>2 the page marked 252, okay, this looks like some</p> <p>3 conceptual discussions about different ways of</p> <p>4 mitigating the risk, does it not?</p> <p>5 A. Am I looking at the proper slide,</p> <p>6 "Improved Membrane (Hydrophobic on both sides)"?</p> <p>7 Q. Yes. As a matter of fact --</p> <p>8 A. Okay.</p> <p>9 Q. Right. If you look at the next</p> <p>10 five pages or so, or four pages, after that, do</p> <p>11 these look all like conceptual -- concepts for</p> <p>12 how to mitigate the risk from the venting being</p> <p>13 blocked?</p> <p>14 A. Yes. That's what they look like.</p> <p>15 Q. Okay. So the first one is</p> <p>16 "Improved Membrane (Hydrophobic on both sides)." And then it looks to me like it talks about the</p> <p>17 benefits and -- or the pluses and the minuses of</p> <p>18 each approach.</p> <p>19 And in this case, the plus of it</p> <p>20 was that it "Mitigates the membrane from becoming</p> <p>21 obstructed," but the -- it looks like the con</p> <p>22 would be "Development would be heavy on process</p> <p>23 and automation."</p>

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<p style="text-align: right;">Page 178</p> <p>1 What does that mean? 2 A. That means that what we talked 3 about earlier then, big concern with -- in 4 selecting the new material was how was it going 5 to act in the high-volume manufacturing 6 environment being used in our automated assembly 7 systems. 8 Q. And then it says, "Proof of 9 Concept demonstrated acceptable Wet Flow 10 Capability." 11 And was that what we talked about 12 before the break, where you had these three 13 materials that all performed vastly better than 14 the Emflon material? 15 A. Right. This basically 16 demonstrated that there are materials on the 17 market that can withstand a certain amount of 18 fluid and remain permeable. 19 Q. Okay. If you turn to the next 20 page, please. 21 A. Yes. 22 Q. Is this another concept that was 23 discussed, "Reservoir to Electronics Chamber 24 Venting"?</p>	<p style="text-align: right;">Page 180</p> <p>1 that was supposed to work? 2 A. It basically means that in the 3 event where uncontrolled delivery would happen, 4 it would empty into -- no, I'm sorry. Strike 5 that. I'm wrong. No, I don't remember this 6 concept. Uh-uh. 7 Q. Okay. And the next bullet point 8 is "Reliability Testing needed to determine 9 performance over 4 years." 10 Is that relating to the life of 11 the -- the life expectancy of the pump? 12 A. Yes, that is correct. 13 Q. So that would have a long lead 14 time in order to validate it and test that 15 particular methodology. Correct? 16 A. That is correct. 17 Q. And I assume that was considered 18 to be a major con for this work-around. Right? 19 A. Yes. 20 Q. All right. But then it noted the 21 "Proof of Concept demonstrated acceptable 22 capabilities with obstructed membrane." 23 How is a proof of concept done 24 for that particular methodology?</p>
<p style="text-align: right;">Page 179</p> <p>1 A. Yes. 2 Q. Can you explain what that concept 3 was? 4 A. I don't remember exactly, but the 5 idea was to vent the reservoir compartment, 6 instead of venting it to the atmosphere or 7 environment, as is done currently, to implement 8 some kind of valve that would let the air go 9 inside the -- essentially housing of the pump. 10 Q. Okay. So it notes that the pros 11 are that it "Mitigates the over-pressurization of 12 the Reservoir Compartment." And it says, "Small 13 reservoir frictions retire large volume to 14 prevent stopper movement." 15 What does that mean? 16 A. "Small reservoir frictions" -- 17 I'm not sure what it means. 18 Q. Okay. And then the next point 19 under it is, "End result is that reservoir could 20 empty before seating is triggered (no 21 over-delivery). Pump would seat with stopper 22 bottomed out and would be followed by a Low 23 Reservoir Alert." 24 Do you -- can you explain how</p>	<p style="text-align: right;">Page 181</p> <p>1 A. I cannot speculate on this, 2 because I have not seen that proof of concept. 3 Q. Okay. If you go to the next 4 page, please, this one is titled "Reservoir 5 Removal Prevention Feature." Okay. 6 Basically this would prevent the 7 user from making that error of removing the 8 reservoir while it's underneath a pressurized 9 insulin vial. Correct? 10 A. Correct. 11 Q. And it notes that the major pro 12 for this is that it "Mitigates the root cause 13 (insulin getting on membrane): locks Reservoir 14 while the Vial is attached." 15 Then it says, it "Only impacts 16 the Transfer Guard Tooling." 17 So that would have been a major 18 plus as well, because it sounds like you wouldn't 19 have had to do a whole major redesign of the 20 transfer guard. Right? 21 MR. MERRELL: Objection to form. 22 THE WITNESS: Well, it's still a 23 major redesign considering the tooling we 24 use.</p>

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<p style="text-align: right;">Page 182</p> <p>1 BY MR. HAVERTY:</p> <p>2 Q. Okay. But --</p> <p>3 A. And -- yeah. Still is.</p> <p>4 Q. And the con that was noted there</p> <p>5 is "Would not prevent the membrane from getting</p> <p>6 wetted in other typical use cases." Right?</p> <p>7 A. Uh-huh, yes.</p> <p>8 Q. What were the other -- what were</p> <p>9 the other typical use cases that were foreseen</p> <p>10 that could lead to the wetting of the membrane</p> <p>11 other than detaching it -- detaching the</p> <p>12 reservoir from the transfer guard while it was</p> <p>13 underneath a pressurized insulin vial?</p> <p>14 A. Again, hard to answer at this</p> <p>15 point. I don't remember. But one was doing this</p> <p>16 within -- within short distance of water source,</p> <p>17 running faucet, shower, something like that.</p> <p>18 Q. Okay. Was this, the reservoir</p> <p>19 removal prevention feature, ever explored any</p> <p>20 further than this apparent conceptual slide, do</p> <p>21 you know?</p> <p>22 A. Not to my knowledge.</p> <p>23 Q. Was there anybody who advocated</p> <p>24 for it, that thought that it was a viable</p>	<p style="text-align: right;">Page 184</p> <p>1 seating -- when actual seating occurs versus air</p> <p>2 incursion.</p> <p>3 Q. And that's because actual seating</p> <p>4 occurs when the slide screw detects a certain</p> <p>5 level of pressure. Right? And then it stops.</p> <p>6 Correct?</p> <p>7 A. That was the idea.</p> <p>8 Q. Do you know what were the</p> <p>9 major -- what was a -- the negative about this</p> <p>10 concept, if you know?</p> <p>11 A. No, I don't.</p> <p>12 Q. Okay. Do you know whether that</p> <p>13 was explored any further than this concept here?</p> <p>14 A. I'm not aware, no.</p> <p>15 Q. Do you know whether those</p> <p>16 work-arounds were actually rejected, or were they</p> <p>17 just -- they just were never pursued any further?</p> <p>18 A. I don't think -- yeah. I don't</p> <p>19 remember how -- how we stopped those -- that</p> <p>20 development. But yeah, to my knowledge, they</p> <p>21 were not pursued any further.</p> <p>22 Q. Okay. If you could look at</p> <p>23 Exhibit 22, please.</p> <p style="text-align: center;">- - -</p>
<p style="text-align: right;">Page 183</p> <p>1 possible risk mitigation?</p> <p>2 A. Don't remember.</p> <p>3 Q. Okay. And then if you turn to</p> <p>4 the next page, please. This looks like it's</p> <p>5 another concept, "Detection of Increasing</p> <p>6 Pressure." And it says, "Detection of whether</p> <p>7 the force increase during seating is caused by</p> <p>8 contacting the stopper or compression of air.</p> <p>9 Development would be heavy on testing and aging</p> <p>10 of devices." And "Review of preliminary data</p> <p>11 demonstrates a capability to develop an algorithm</p> <p>12 for both Paradigm and NGP.</p> <p>13 By the way, what is NGP?</p> <p>14 A. It's an abbreviation for new</p> <p>15 generation pump.</p> <p>16 Q. All right. Can you -- and as</p> <p>17 best you can, explain it to people who are not</p> <p>18 engineers, can you explain what this concept is</p> <p>19 discussing?</p> <p>20 A. To the best of my knowledge, this</p> <p>21 was a software approach to -- to embed into the</p> <p>22 pumps software that will detect -- it will be</p> <p>23 able to tell the difference between when it's --</p> <p>24 when the occlusion is caused -- or when it's</p>	<p style="text-align: right;">Page 185</p> <p>1 (Deposition Exhibit No. AA-22,</p> <p>2 Engineering Reports, ER13-8302 Version A,</p> <p>3 06/28/2013, Bates stamped</p> <p>4 MDT-BRACP-029066 through</p> <p>5 MDT-BRACP-029082, was marked for</p> <p>6 identification.)</p> <p style="text-align: center;">- - -</p> <p>8 BY MR. HAVERTY:</p> <p>9 Q. Do you have that?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And this is an engineering</p> <p>12 report that you prepared at the end of June of</p> <p>13 2013. Correct? And it basically was a</p> <p>14 synopsis --</p> <p>15 A. Looks like it.</p> <p>16 Q. I'm sorry.</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And it basically is a</p> <p>19 synopsis of the events that occurred from the</p> <p>20 original complaint back in the fall of 2012</p> <p>21 through the investigation, the engineering</p> <p>22 investigation and the other analyses that were</p> <p>23 done. Correct?</p> <p>24 A. Correct.</p>

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<p style="text-align: right;">Page 186</p> <p>1 Q. So this would be a good -- a good 2 summary of all the events that occurred up 3 through the end of June 2013. Right? 4 A. Right. 5 Q. Okay. And actually, it contains 6 most of the events that we discussed already. 7 Correct? 8 A. That is correct. 9 Q. All right. If you could take a 10 look at Exhibit 23, please.</p> <p style="text-align: center;">- - -</p> <p>12 (Deposition Exhibit No. AA-23, 13 Memo dated July 31, 2013, Bates stamped 14 MDT-BRACP-0051047 through 15 MDT-BRACP-0051050, was marked for 16 identification.)</p> <p style="text-align: center;">- - -</p> <p>18 THE WITNESS: Okay.</p> <p>19 BY MR. HAVERTY:</p> <p>20 Q. Do you have that?</p> <p>21 A. I do.</p> <p>22 Q. Okay. Do you see this appears to 23 be a summary of meeting minutes between 24 representatives from Medtronic and the FDA, July</p>	<p style="text-align: right;">Page 188</p> <p>1 A. She's still with Medtronic in a 2 different capacity. 3 Q. Okay. What is she doing now? 4 A. She is a senior quality director. 5 Q. Okay. And it looks like it lists 6 five meeting action items. 7 And it's -- it was "Medtronic to 8 advise FDA on the decision related to the updated 9 keypad and the installed base of 510(k) pumps. 10 With a further discussion on the issue of how to 11 incorporate improvements into all pumps in the 12 marketplace." 13 Do you know anything about what 14 that discussion was about? 15 A. No, I don't. 16 Q. Do you know what it's referring 17 to as "the installed base of 510(k) pumps"?</p> <p>18 A. No, I don't. 19 Q. Do you know what a 510(k) pump 20 is? 21 A. No, I don't. 22 Q. Do you know what the 510(k) 23 process is? Do you know what that refers to? 24 A. I do know what it refers to. I'm</p>
<p style="text-align: right;">Page 187</p> <p>1 31st of 2013. It was held at the FDA Office of 2 Compliance. 3 You're not listed as an attendee, 4 but did you ever interact with the FDA over any 5 of the issues relating to the prime/fill anomaly 6 CAPA? 7 A. No, I never did. 8 Q. Did you ever provide any 9 information to anybody at Medtronic who was then 10 interacting with the FDA regarding issues 11 surrounding the prime/fill anomaly? 12 A. Yes. 13 Q. Okay. Who did you provide 14 information to? 15 A. Norma Ojeda. 16 Q. She's listed as one of the 17 attendees here. Correct? 18 A. Correct. 19 Q. And she's listed as a senior 20 engineering manager. 21 Was she your supervisor? 22 A. Correct. She was at the time. 23 Q. Okay. Is she no longer with 24 Medtronic?</p>	<p style="text-align: right;">Page 189</p> <p>1 not sure how the process actually works. 2 Q. Okay. Well, what does it -- what 3 does it refer to? What's your understanding of 4 it? What's the 510(k) referring to there? 5 A. It's a -- it's a type of 6 submission that FDA would require in certain new 7 products or changes or whatever else happens in 8 our business. It's an FDA submission, a type of. 9 Q. And in fact -- and we're going to 10 get to this in a little while, but there was a 11 510(k) submission related to the new membrane 12 material for the P-cap connector. Right? 13 A. That is correct. 14 Q. All right. Then the second one 15 is "Medtronic Diabetes to inform FDA related to 16 the effectiveness of product update cards in 17 disposable shipments." 18 Do you know what that's referring 19 to? 20 A. No, I don't. 21 Q. Do you know what the product 22 update cards are? 23 A. Not really, no. 24 Q. Medtronic -- third item,</p>

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<p style="text-align: right;">Page 190</p> <p>1 "Medtronic Diabetes to share with FDA how we get 2 information related to product updates to 3 physicians who do not receive product." 4 Do you know what that's referring 5 to? 6 A. Nope. 7 Q. Okay. Fourth item, "Medtronic to 8 update procedure to include completed Health 9 Hazard Assessments in 806 notifications to" the 10 "FDA." 11 Do you know what that's referring 12 to? 13 A. No, I don't. 14 Q. Do you know what 806 15 notifications are? 16 A. No, nothing specific. 17 Q. Okay. Then Item 5, "Medtronic to 21 update field communication matrix and schedule a 22 follow up meeting discussing the risk definitions 23 and frequency levels with" the "FDA." 24 Do you see that? Do know what</p>	<p style="text-align: right;">Page 192</p> <p>1 Do you know what that's referring 2 to? 3 A. No, I actually don't. 4 Q. All right. 5 A. Not in this context. 6 Q. Okay. 7 A. Not in this context. 8 Q. The next one, "Field Corrective 9 Action-Motor support disc," do you know what 10 issues were surrounding the motor support disc? 11 A. Not really. 12 Q. Then the next one, turn to the 13 next page, if you would. It has the "Field 14 Corrective Action-Vent Block." 15 You do know about that. Right? 16 A. I do. 17 Q. And then it goes on to say, "John 18 Diehl and Carl Fischer asked if a health hazard 19 assessment was done and if so was it provided?" 20 We know that a health hazard 21 assessment was done. Correct? 22 A. It was done. I don't know a time 23 reference between this and -- when this meeting 24 occurred and when the HHA was done for this</p>
<p style="text-align: right;">Page 191</p> <p>1 that's referring to? 2 A. No, I don't. 3 Q. Okay. All right. In any event, 4 if you turn to the next page, please. It lists a 5 number of issues that were discussed, apparently 6 were discussed at this meeting, the first being 7 the "Keypad Improvement slide." 8 Do you know what that's referring 9 to? 10 A. No. 11 Q. Then the second one is "Motor 12 Error Phase II slide." 13 Do you know what that is 14 referring to? 15 A. No, I don't. 16 Q. Do you know what the motor error 17 is dealing with? 18 A. No. 19 Q. Do you know -- and if you look at 20 the next one, "Motor Support Disc," do you know 21 what that's referring to? 22 A. Nope, I don't. 23 Q. The next one is "Moisture 24 Ingress."</p>	<p style="text-align: right;">Page 193</p> <p>1 particular case. 2 Q. Okay. We saw that the health 3 hazard evaluation was done in the spring of 2013. 4 Right? 5 A. I don't remember from the 6 documents. 7 Q. And then it says, "Mr. Fischer 8 further clarified that going forward whenever 9 Medtronic Diabetes submits an 806, FDA would 10 appreciate if you would provide a health hazard 11 assessment." 12 Do you know what that's referring 13 to? 14 A. No. 15 Q. And then the next bullet point, 16 it says, "Dr. Beaston inquired if Medtronic 17 Diabetes is planning a better correction than 18 just telling patients what to avoid?" 19 Were you aware of that, that the 20 FDA was interested in whether or not FDA -- 21 Medtronic was going to do more than simply send 22 out the "dear healthcare provider" letters or the 23 "dear patient" letters? 24 A. No, I'm not aware of the</p>

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<p>1 communication.</p> <p>2 Q. Okay. But then Jeff Hubauer --</p> <p>3 who is Jeff Hubauer?</p> <p>4 A. Jeff Hubauer was -- I don't know</p> <p>5 at the time, vice president of Medtronic</p> <p>6 Diabetes.</p> <p>7 Q. All right. He informed the FDA</p> <p>8 people "that design changes are being evaluated</p> <p>9 and that we expect to go to new vent membrane to</p> <p>10 eliminate this issue."</p> <p>11 So that was the thinking -- that</p> <p>12 was Medtronic's approach at that time. Correct?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. If you could look at</p> <p>15 Exhibit 24, please.</p> <p>16 - - -</p> <p>17 (Deposition Exhibit No. AA-24,</p> <p>18 Email chain, top one dated August 08,</p> <p>19 2013, Bates stamped MDT-BRACP-0067708 and</p> <p>20 MDT-BRACP-0067709, was marked for</p> <p>21 identification.)</p> <p>22 - - -</p> <p>23 BY MR. HAVERTY:</p> <p>24 Q. Do you have that?</p>	<p>1 A. That slide probably led to that</p> <p>2 report. I don't exactly remember when we</p> <p>3 released that.</p> <p>4 Q. Okay. Beyond doing the blocked</p> <p>5 vent testing, and you found that Versapor was the</p> <p>6 best risk mitigator of all the materials tested,</p> <p>7 did you then -- or what did you do next at that</p> <p>8 point?</p> <p>9 MR. MERRELL: Objection to form.</p> <p>10 THE WITNESS: Are you asking me</p> <p>11 what were the steps we took after</p> <p>12 identifying Versapor 450 as a replacement</p> <p>13 material? Did I understand you</p> <p>14 correctly?</p> <p>15 BY MR. HAVERTY:</p> <p>16 Q. Yes. I mean, when did you make</p> <p>17 the decision to pursue Versapor as your basic</p> <p>18 solution?</p> <p>19 A. Upon completion -- upon</p> <p>20 completion of the comparison testing for three</p> <p>21 materials.</p> <p>22 Q. We talked --</p> <p>23 A. It was basically -- yes.</p> <p>24 Correct. It was determined that any of those</p>
<p>Page 195</p> <p>1 A. I do.</p> <p>2 Q. Okay. Who is Amichai Vardi?</p> <p>3 A. Amichai Vardi was a quality</p> <p>4 director at that time.</p> <p>5 Q. Okay. And the second email on</p> <p>6 this chain is from Amichai Vardi to a number of</p> <p>7 people, including you, dated August 6, 2013.</p> <p>8 Correct?</p> <p>9 A. Uh-huh. Correct.</p> <p>10 Q. And at this point, in August of</p> <p>11 2013, had you -- had you made a decision to go</p> <p>12 ahead and explore the Versapor 450 more fully at</p> <p>13 that point?</p> <p>14 A. I don't remember. I need to</p> <p>15 refer to the -- to our engineering report</p> <p>16 documentation.</p> <p>17 Q. Of the engineering -- your</p> <p>18 engineering report from the end of June?</p> <p>19 A. No, no, not my engineering</p> <p>20 report. It's from Benjamin Grover, the report</p> <p>21 that -- where he compares the materials.</p> <p>22 Q. Okay. But do you recall around</p> <p>23 when that was -- is that that slide deck we were</p> <p>24 talking about?</p>	<p>Page 197</p> <p>1 three will be a good candidate as a replacement,</p> <p>2 but we choose Versapor 450.</p> <p>3 Q. Okay. And that was a product</p> <p>4 that was made by Pall, who was the current</p> <p>5 manufacturer -- or current supplier of the Emflon</p> <p>6 material that was currently in the P-caps.</p> <p>7 Right?</p> <p>8 A. Correct, yes.</p> <p>9 Q. So what was the next step then</p> <p>10 once you settled on Versapor as your material of</p> <p>11 choice? What did you do next?</p> <p>12 A. Next high-level step was to see</p> <p>13 how it would act in the -- in the assembly</p> <p>14 machine and then subsequently validate it.</p> <p>15 Q. Okay. How did you go about that</p> <p>16 process? You had to obtain --</p> <p>17 A. We created a -- we created a part</p> <p>18 number specific to the form that we needed to</p> <p>19 receive that material in, and then we commenced</p> <p>20 or commissioned our supplier to -- that possessed</p> <p>21 one of the cap assembly -- we refer to them as</p> <p>22 cap assembly machines, the assembly cells that</p> <p>23 assembled P-caps, to create and develop a process</p> <p>24 for the Versapor 450 with a subsequent ID to go</p>

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<p style="text-align: center;">Page 198</p> <p>1 into validation.</p> <p>2 Q. Okay. How, if at all, did the</p> <p>3 manufacturer of the membrane with the Versapor on</p> <p>4 this CAM machine differ from the Emflon?</p> <p>5 A. I'm sorry. I'm not clear on the</p> <p>6 question.</p> <p>7 Q. Yeah. I probably need to lay a</p> <p>8 better foundation.</p> <p>9 So was the idea that you're going</p> <p>10 to use the Versapor as a single-membrane</p> <p>11 material, or were you going to use the Versapor</p> <p>12 in combination with the hydrophobic PTFE that was</p> <p>13 already in the membrane?</p> <p>14 A. No. Versapor 450 is a material</p> <p>15 of its own that is hydrophobic and would provide</p> <p>16 enough -- enough protection that we were looking</p> <p>17 for.</p> <p>18 Q. So you're only going now with a</p> <p>19 single-layer membrane. Right?</p> <p>20 A. It's single material of membrane.</p> <p>21 I don't remember -- I don't think Versapor is</p> <p>22 constructed with a single layer of material. But</p> <p>23 it's a material as the supplier makes it.</p> <p>24 Q. Let me go back then.</p>	<p style="text-align: center;">Page 200</p> <p>1 the materials on the machine to determine what</p> <p>2 width you needed Pall to manufacture it to?</p> <p>3 A. No. We -- we knew the -- the</p> <p>4 width never changed from Emflon to Versapor 450.</p> <p>5 What we needed to do is to develop -- so the</p> <p>6 membrane material is welded via ultrasonic</p> <p>7 welding process to the plastic housing. We</p> <p>8 needed to develop a new --</p> <p>9 Q. I'm sorry, what --</p> <p>10 A. And we needed to develop a new --</p> <p>11 Q. I missed the last part of that.</p> <p>12 A. I'm sorry.</p> <p>13 Q. My fault.</p> <p>14 A. We needed to develop a new</p> <p>15 welding process for the new material, because the</p> <p>16 old process wouldn't work for it.</p> <p>17 Q. And how did the old process not</p> <p>18 work? What was the problem?</p> <p>19 A. It would burn holes in the new</p> <p>20 material, as one of the examples.</p> <p>21 Q. Anything else?</p> <p>22 A. Not at that point.</p> <p>23 Q. Okay. So sometime in the spring</p> <p>24 or early summer of 2013, you settled on the</p>
<p style="text-align: center;">Page 199</p> <p>1 Because what you would have to do</p> <p>2 with the Emflon membrane was you had to weld or</p> <p>3 you had to join the polyester and the PTFE,</p> <p>4 correct, as part of the manufacturing process?</p> <p>5 A. This is proprietary to Pall -- to</p> <p>6 Pall corporation. I have no idea how they -- in</p> <p>7 fact, we wanted to see how they manufactured it,</p> <p>8 and they wouldn't allow us.</p> <p>9 Q. So just so I understand, the</p> <p>10 material came to you already as a two-layer --</p> <p>11 the PTFE and the woven -- nonwoven polyester from</p> <p>12 Pall. Correct?</p> <p>13 A. Correct.</p> <p>14 Q. And that's what I'm trying to</p> <p>15 understand. The Versapor then, whatever</p> <p>16 component -- constituent parts it has in it, came</p> <p>17 to you from Pall as a finished product, a</p> <p>18 finished membrane. Correct?</p> <p>19 A. Correct. The only customization</p> <p>20 of that material will be -- would be the width to</p> <p>21 which it was slit to fit the machine.</p> <p>22 Q. Okay. And that's what I was</p> <p>23 trying to understand.</p> <p>24 So you needed to validate or test</p>	<p style="text-align: center;">Page 201</p> <p>1 Versapor, and you attempted to get materials from</p> <p>2 Pall so that you could test it out on the -- on</p> <p>3 your manufacturing equipment and figure out how</p> <p>4 it would work with the CAM machines. Correct?</p> <p>5 A. Correct.</p> <p>6 Q. So do you recall the period of</p> <p>7 time when that type of validation was going on in</p> <p>8 terms of the sonic welding and whatever else you</p> <p>9 needed to do to get that membrane into the cap?</p> <p>10 A. No. I don't remember the exact</p> <p>11 time frame when that was happening.</p> <p>12 Q. But was that going on during the</p> <p>13 summer and the fall of 2013?</p> <p>14 A. Again, I don't remember. It's</p> <p>15 all documented in our reports, but I don't</p> <p>16 remember exactly off the top of my head right</p> <p>17 now.</p> <p>18 Q. Okay. If you could look at</p> <p>19 Exhibit 25, please.</p> <p>20 - - -</p> <p>21 (Deposition Exhibit No. AA-25,</p> <p>22 Engineering Change Form, ECR/ECO:</p> <p>23 5-46903, Bates stamped MDT-BRACP-0062972</p> <p>24 through MDT-BRACP-0062976, was marked for</p>

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1 identification.) 2 - - - 3 THE WITNESS: Okay. 4 BY MR. HAVERTY: 5 Q. This is an Engineering Change 6 Form dated 9/18/2013. And it notes that the 7 summary of the change is "FDA required update to 8 infusion set artwork to add caution and warnings 9 regarding blocked vents issue. Release prototype 10 and production versions of artwork required to 11 ensure patient safety." And it says the "Reason 12 For Change, FDA required update for patient 13 safety." 14 And then it says, 15 "Qualifying/Validation, No new claims. Changes 16 are required per FDA to ensure patient safety and 17 warnings about potential harm if blocked vents 18 occur." 19 Do you see that? 20 A. Yes, I do. 21 Q. Do you recall what those 22 instructions were, what the warnings were? 23 A. Yes. 24 Q. What were they?	Page 202 1 A. Yes. 2 Q. It starts off with -- it starts 3 off with "Indications For Use." 4 A. Yes. 5 Q. Right? And then underneath that, 6 it says "Warnings." Right? 7 A. Yes. 8 Q. And if you go over to the next 9 column, on the second paragraph, it says, "If 10 insulin, or any liquid," gels -- excuse me -- 11 "gets inside the tubing connector, it can 12 temporarily block the vents that allow the pump 13 to properly fill the infusion set. This may 14 result in the delivery of too" much -- "too 15 little or too much insulin, which can cause 16 hyperglycemia or hypoglycemia. If this occurs, 17 start over with a new reservoir and infusion 18 set." 19 Is that the updated warning that 20 you recall the FDA required? 21 A. That is. 22 Q. And if you go over to the first 23 column there, the very top of it, it says on 24 there, "Refer to pump and infusion set user
Page 203 1 A. This -- we were -- within this 2 change form, we were adding to the warnings 3 section of every IFU of an infusion set. We were 4 adding a wording against presence of insulin or 5 any other fluid. I don't remember the exact 6 verbiage, but that's the essence. 7 Q. Okay. If you could, please, look 8 at Exhibit 26. 9 - - - 10 (Deposition Exhibit No. AA-26, 11 MiniMed Reservoir Instructions for Use, 12 Bates stamped MDT-BRACP-028899 and 13 MDT-BRACP-028900, was marked for 14 identification.) 15 - - - 16 THE WITNESS: Go ahead. 17 BY MR. HAVERTY: 18 Q. You have it. Okay. 19 If you could go to the second 20 page of that. 21 A. Okay. 22 Q. All right. Up at the top left, 23 like first column -- second column over, do you 24 see there's a thing in English? Do you see that?	Page 205 1 guides for installation and filling." 2 Do you see that? 3 A. Yes. 4 Q. Do you recall whether that was a 5 new instruction on this information for users? 6 A. No, I don't recall. 7 Q. By the way, just so we're clear 8 for the record, this Exhibit 26 is the IFU for 9 the MiniMed reservoirs. Correct? 10 A. Correct. 11 Q. And the IFUs are the documents 12 that accompany the disposables in the boxes in 13 which they're shipped to consumers. Correct? 14 A. Correct. 15 Q. If you then could look at 16 Exhibit 27, please. 17 - - - 18 (Deposition Exhibit No. AA-27, 19 Medtronic Quick-set Instructions for Use, 20 Bates stamped MDT-BRACP-028901 and 21 MDT-BRACP-028902, was marked for 22 identification.) 23 - - - 24 BY MR. HAVERTY:

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<p>1 Q. And this is the IFU for the 2 Medtronic Quick-set infusion sets. Correct? 3 A. Correct. One of them, yes. 4 Q. And if you look at the -- 5 underneath the Medtronic logo, there is a -- in 6 that black-lined box there, there is the first 7 thing, it says, "Refer to pump and reservoir user 8 guides for installation and priming." 9 Do you see that? 10 A. Yes, I do. 11 Q. Okay. Do you know whether that 12 was new information, a change in these labels? 13 A. I don't remember if it was new 14 information. 15 Q. Okay. And if you look at the 16 pictograph number 3, do you see that? 17 A. Yes, I do. 18 Q. It looks like it has two 19 connectors depicted there. One on the left top 20 part, it appears to be a P-cap being connected to 21 a reservoir. 22 Do you see that? 23 A. Yes. 24 Q. And in the one to the right, in</p>	<p>1 for the Quick-sets, so why is it depicting a Luer 2 Lock in addition to a P-cap connector, if you 3 know? 4 A. Because -- because Medtronic 5 markets Quick-set infusion sets with both 6 connectors. 7 Q. And by the way, the Luer Lock 8 connector wouldn't suffer from the same problem 9 as the proprietary connector because it doesn't 10 rely upon venting. Correct? 11 A. Correct. It's completely 12 different physics, yes. 13 Q. Was there any consideration given 14 to developing a Luer Lock connector for the 15 reservoirs that would not have the venting 16 problem that the P-cap had? 17 A. Not that I remember. 18 Q. Do you remember any discussion 19 about it at all? 20 A. I don't. 21 Q. If you could turn to the second 22 page, please. 23 A. Okay. 24 Q. All right. If you go down --</p>
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<p>1 the lower portion of it, it looks like a 2 different type of connector onto the reservoir, 3 does it not? 4 A. Correct. It does. 5 Q. Is that -- is that a Luer Lock 6 connector? 7 A. It is a Luer Lock connector, yes. 8 Q. So are you able to tell what type 9 of reservoir that is that's being depicted there 10 that can be used with a Luer Lock connector? 11 A. There's only one reservoir that 12 Medtronic manufactures that can be connected to a 13 Luer Lock connector. 14 Q. And what was that? 15 A. I don't remember the model 16 number. 17 Q. Well, would that reservoir work 18 in a MiniMed pump? 19 A. No, it wouldn't. 20 Q. Okay. What pumps would it -- 21 would it only work in? 22 A. Whichever pumps by other 23 manufacturers that can utilize such reservoir. 24 Q. Well, this is -- this is an IFU</p>	<p>1 never mind. 2 If you can go to Exhibit 28, 3 please. 4 - - - 5 (Deposition Exhibit No. AA-28, 6 Medtronic MiniMed Paradigm Reservoir 7 Instructions for Use, Bates stamped 8 MDT-BRACP-028897 and MDT-BRACP-028898, 9 was marked for identification.) 10 - - - 11 THE WITNESS: Okay. 12 BY MR. HAVERTY: 13 Q. All right. You recognize this as 14 an IFU for MiniMed reservoirs? 15 A. Okay. 16 Q. Do you recognize this as the IFU 17 that was in use prior to the discovery of the 18 prime/fill anomaly or the temporary vent block? 19 A. I am not sure which one was used 20 when in reference to reservoirs. 21 Q. Okay. If you could take a look 22 at page 2. 23 A. Okay. 24 Q. Do you agree with me that the</p>

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<p style="text-align: right;">Page 210</p> <p>1 warning that was in -- I guess it was Exhibit 26, 2 about insulin or anything getting on the 3 reservoir top is not contained in this reservoir 4 IFU?</p> <p>5 A. I would agree, yes.</p> <p>6 Q. Okay. And in fact, at the bottom 7 there, after pictograph number 10 to the right of 8 that, it says differently than the one in 9 Exhibit 26, "Refer to Paradigm Pump User Guide 10 for inserting reservoir, priming pump, and 11 inserting infusion set." Correct?</p> <p>12 A. Correct.</p> <p>13 Q. The new -- newer warning, the 14 updated warning, referred the user to the user 15 guide for the filling instructions as well. 16 Correct? If you want to take a look at it.</p> <p>17 A. Yes.</p> <p>18 Q. If you could take a look at 19 Exhibit 30, please.</p> <p>20 - - -</p> <p>21 (Deposition Exhibit No. AA-30, 22 PowerPoint, "Temporary Vent Block During 23 Prime CAPA (QIT13-006)," Bates stamped 24 MDT-BRACP-0054462 through</p>	<p style="text-align: right;">Page 212</p> <p>1 to, somewhere in 2009 we lost the ability to pass 2 air through the membranes. Correct?</p> <p>3 A. Yeah. Actually, even earlier 4 than then.</p> <p>5 Q. Where does it appear on this 6 graph?</p> <p>7 A. I think it has a stamp -- it's 8 very blurry here, but I think it has a stamp of 9 2000 -- October of 2008.</p> <p>10 Q. Okay. And the top line graph, 11 what is that depicting? What is that referring 12 to?</p> <p>13 A. That's air flow through the 14 membrane in the dry condition.</p> <p>15 Q. Okay. So as it goes off to the 16 right -- and then it goes way up to 80 -- 17 what's -- SCCM and above that, what is that -- is 18 that saying that's good air flow in the dry 19 membrane?</p> <p>20 A. That's very good air flow, yes.</p> <p>21 Q. Okay. And then the one that's 22 underneath of it reflects the air flow through a 23 wet membrane. Correct?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 211</p> <p>1 MDT-BRACP-0054469, was marked for 2 identification.)</p> <p>3 - - -</p> <p>4 THE WITNESS: Okay.</p> <p>5 BY MR. HAVERTY:</p> <p>6 Q. This is a PowerPoint slide deck 7 titled "Temporary Vent Block During Prime CAPA... 8 Project Summary," and it's got your name on it, 9 from December 12, 2013. Correct?</p> <p>10 A. Yes.</p> <p>11 Q. And I take it from that, this was 12 a presentation that you made to explain where you 13 were in the CAPA process as of the end of 2013. 14 Correct?</p> <p>15 A. Correct.</p> <p>16 Q. If you could look at second page 17 of this.</p> <p>18 A. Okay.</p> <p>19 Q. What is that graph meant to 20 depict?</p> <p>21 A. This graph shows the testing of 22 historical samples of hardware that we could 23 obtain that we spoke about earlier today.</p> <p>24 Q. Okay. And that's where you refer</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. And what it shows is that at some 2 point, it was as high as 22 or so. And then it 3 dropped to under 10 and continued on its way down 4 to where it got to basically 0. Correct?</p> <p>5 A. Correct.</p> <p>6 Q. If you turn to the next page, 7 please.</p> <p>8 A. Okay.</p> <p>9 Q. And what is this slide meant to 10 depict?</p> <p>11 A. This shows -- this shows how we 12 utilize -- how the team utilized a tool cause -- 13 called root cause investigation analysis or root 14 cause analysis to determine potential causes of 15 an issue and to kind of evaluate them as to which 16 are more probable or more important to go after 17 and separate them from the ones that we deemed 18 insignificant at that point.</p> <p>19 Q. Okay. So what does this tell you 20 about what the root causes were and what things 21 were most significant?</p> <p>22 A. So it tells -- tells us that the 23 most significant were the membrane material 24 itself, the CAM machine, as in what could CAM</p>

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<p style="text-align: right;">Page 214</p> <p>1 machine -- could it have altered the material in 2 any shape or form during manufacturing to create 3 such condition.</p> <p>4 Q. Right.</p> <p>5 A. And then the weld horn design, 6 that's going into more details within CAM 7 machine. Weld horn is not -- weld horn is a 8 tool -- one of the tools that is used inside the 9 CAM machine to attach the membrane to the plastic 10 P-cap housing.</p> <p>11 Q. Okay. And were you ultimately 12 able to determine whether the CAM was responsible 13 or the weld horn design was responsible?</p> <p>14 A. No. We eventually ruled both of 15 those out.</p> <p>16 Q. So it got down to the point where 17 you realized it was purely a function of the 18 membrane material. Right?</p> <p>19 A. Correct. Yes.</p> <p>20 Q. All right. If you go to the next 21 slide, please.</p> <p>22 A. Okay.</p> <p>23 Q. You've got -- you described the 24 problem, the membrane becomes gas impermeable</p>	<p style="text-align: right;">Page 216</p> <p>1 filling technique. Correct?</p> <p>2 A. That is correct.</p> <p>3 Q. If you turn to the next page 4 then. 5 So you talk about the "Material, 6 5 potential materials identified (3 from 7 current supplier and 2 from a potentially new 8 supplier)." 9 You eliminated two of those. 10 Correct? 11 A. Correct. 12 Q. Well, you noted "PCAP assembly 13 samples built using 5 prospective materials and 14 3 times sterilized." And then "Preliminary 15 testing eliminated 2 materials." 16 What was the preliminary testing 17 that was done that eliminated two of the 18 materials? 19 A. If I remember correctly, both wet 20 and -- wet -- dry and wet flow. 21 Q. Okay. The wet flow was 22 unacceptable? 23 A. I don't remember exactly the 24 cause that we eliminated for the first two</p>
<p style="text-align: right;">Page 215</p> <p>1 when liquid is deposited on it and how that 2 happens.</p> <p>3 And then you note that "Membrane 4 material needs to be replaced with material that 5 will remain gas permeable when temporary wet." 6 Right?</p> <p>7 A. Right.</p> <p>8 Q. And that was at that point, at 9 least as of the end of 2013, that was the 10 direction that the CAPA was headed. Correct?</p> <p>11 A. Correct.</p> <p>12 Q. And then you note that the 13 "Amount of liquid permitted on membrane needs to 14 be determined." Right?</p> <p>15 A. Correct.</p> <p>16 Q. And that ultimately became the 17 wet flow spec. Right?</p> <p>18 A. That is correct.</p> <p>19 Q. If you turn to the next slide, 20 please.</p> <p>21 That's the "'Wet' Spec 22 Development." We talked about that earlier. 23 This is determining how much insulin would get 24 deposited if somebody followed an improper</p>	<p style="text-align: right;">Page 217</p> <p>1 materials, but yeah. One of them was a wet flow. 2 Wet flow unacceptable or inconsistent. 3 Q. Okay. If you turn to the next 4 page, please. 5 You note "New Material 6 Selection." The "3 Remaining materials underwent 7 array of functional testing." 8 And "Per results of preliminary 9 testing all 3 materials are promising for 10 production." Correct? 11 A. Correct. 12 Q. So then if you turn to the next 13 slide, as of December of 2013, your plan was to 14 finalize the reports for the mechanical testing 15 and wet flow spec development. And then Develop 16 and document specification for wet flow. Create 17 part numbers for all 3 materials. Procure 18 'validation' quantity of all 3 materials. And 19 Develop preliminary welding process window. 20 Develop a validation plan and schedule. Right? 21 A. Right. 22 Q. And so based upon this report in 23 December of 2013, were you pretty much on 24 schedule with the projected schedule that we</p>

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<p>1 discussed from the CAPA report?</p> <p>2 A. I don't remember. I need to</p> <p>3 refer back to the schedule.</p> <p>4 Q. Okay. You were -- the original</p> <p>5 plan from Exhibit 2 on page 42 said that you were</p> <p>6 getting -- you expected to identify alternative</p> <p>7 materials as of October 15, 2013.</p> <p>8 So you were on schedule with</p> <p>9 that. Right?</p> <p>10 A. We were on schedule for that,</p> <p>11 yes.</p> <p>12 Q. And then -- I'm sorry. I was</p> <p>13 looking at the wrong page. Page 8, by the way.</p> <p>14 MS. MARTINEZ: Of what exhibit?</p> <p>15 THE WITNESS: Number 2.</p> <p>16 MR. HAVERTY: Page 8.</p> <p>17 THE WITNESS: I lost it. Sorry.</p> <p>18 One second. Right here.</p> <p>19 BY MR. HAVERTY:</p> <p>20 Q. Yeah.</p> <p>21 A. Here, page 8. I got it.</p> <p>22 Q. Okay. As of December of 2013,</p> <p>23 were you on schedule to validate the assembly</p> <p>24 process using new material?</p>	<p>1 A. Okay.</p> <p>2 Q. Do you know why that was pushed</p> <p>3 back?</p> <p>4 A. No. I don't remember why.</p> <p>5 Q. All right. If you could look at</p> <p>6 Exhibit 32, please.</p> <p>7 - - -</p> <p>8 (Deposition Exhibit No. AA-32,</p> <p>9 PowerPoint, "Temporary Vent Block During</p> <p>10 Prime CAPA (QIT13-006)," Bates stamped</p> <p>11 MDT-BRACP-0069836 through</p> <p>12 MDT-BRACP-0069847, was marked for</p> <p>13 identification.)</p> <p>14 - - -</p> <p>15 BY MR. HAVERTY:</p> <p>16 Q. You've got that?</p> <p>17 A. I do, yes.</p> <p>18 Q. This is another PowerPoint slide</p> <p>19 deck entitled "Temporary Vent Block During Prime</p> <p>20 CAPA...Project Summary 1/28/2014," about six</p> <p>21 weeks after the one that you did in December.</p> <p>22 Correct?</p> <p>23 A. Correct.</p> <p>24 Q. Is this a PowerPoint slide deck</p>
<p>1 A. Yes.</p> <p>2 Q. And let me qualify that a little</p> <p>3 bit.</p> <p>4 If you look back at page 42 as</p> <p>5 well, is this a more updated action plan</p> <p>6 because -- I mean, sorry.</p> <p>7 Was this the original action plan</p> <p>8 from August of 2013?</p> <p>9 And the reason I ask is because</p> <p>10 number 2, "Validate Assembly Process Using New</p> <p>11 Material" had a due date at that point as of</p> <p>12 February 14, 2014.</p> <p>13 Did that get moved? Did that get</p> <p>14 pushed up?</p> <p>15 A. It may have been.</p> <p>16 Q. Okay. Do you know why it was</p> <p>17 moved from February of 2004 to May of 2004? Or</p> <p>18 '14, excuse me.</p> <p>19 A. Probably we -- no. I don't</p> <p>20 remember exactly why it got moved.</p> <p>21 Q. Okay. And then because the</p> <p>22 design review on page 8 was due on 4/24/2014, and</p> <p>23 it looks like the original schedule was for that</p> <p>24 to be in February of 2014?</p>	<p>1 that you created?</p> <p>2 A. Yes.</p> <p>3 Q. All right. And it looks pretty</p> <p>4 much the same as the one from December. As a</p> <p>5 matter of fact, it looks exactly the same as the</p> <p>6 one from December.</p> <p>7 Do you know why there was another</p> <p>8 PowerPoint slide deck that was created six weeks</p> <p>9 after the other one that didn't really contain</p> <p>10 any new information?</p> <p>11 A. No, I don't remember why.</p> <p>12 Q. Do you know what stage the</p> <p>13 process of developing the new membrane material</p> <p>14 was at that point?</p> <p>15 A. No, I don't remember exactly.</p> <p>16 Q. Okay. But you would -- were you</p> <p>17 in the process at that point of developing the</p> <p>18 wet flow spec?</p> <p>19 A. Again, I can't remember without</p> <p>20 referring to documentation.</p> <p>21 MR. HAVERTY: Can we take a real</p> <p>22 quick break here?</p> <p>23 MR. MERRELL: Sure.</p> <p>24 MR. HAVERTY: I'm going to shift</p>

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<p style="text-align: right;">Page 222</p> <p>1 gears.</p> <p>2 THE WITNESS: Okay.</p> <p>3 MR. HAVERTY: Thanks.</p> <p>4 THE VIDEOGRAPHER: We are now</p> <p>5 going off the record, and the time is</p> <p>6 2:47 p.m.</p> <p>7 - - -</p> <p>8 (A recess was taken from 2:47</p> <p>9 p.m. to 2:58 p.m.)</p> <p>10 - - -</p> <p>11 THE VIDEOGRAPHER: We are now</p> <p>12 going back on the record, and the time is</p> <p>13 2:58 p.m.</p> <p>14 BY MR. HAVERTY:</p> <p>15 Q. Mr. Aleksandrovich, if you could</p> <p>16 look at Exhibit 52, please.</p> <p>17 A. 52?</p> <p>18 Q. 52, yeah.</p> <p>19 - - -</p> <p>20 (Deposition Exhibit No. AA-52,</p> <p>21 Email chain, top one dated February 06,</p> <p>22 2014, Bates stamped MDT-BRACP-0050992</p> <p>23 through MDT-BRACP-0050994, was marked for</p> <p>24 identification.)</p>	<p style="text-align: right;">Page 224</p> <p>1 Office via US Postal Service. I addressed the</p> <p>2 letter to the Recall Coordinator (rather than you</p> <p>3 personally) so that it will be delivered to</p> <p>4 whoever is filling in for you in the event you</p> <p>5 are out of the office."</p> <p>6 And then Mr. Tupper goes on to</p> <p>7 say, "At this point" -- and this is as of</p> <p>8 December 11, 2013. "At this point, we believe</p> <p>9 that we have taken all steps within reason to</p> <p>10 ensure that all affected patients have been</p> <p>11 notified. In light of this, we are also</p> <p>12 requesting that FDA consider changing the status</p> <p>13 of this recall to completed."</p> <p>14 Were you aware of the fact that</p> <p>15 Medtronic made a request of the FDA in December</p> <p>16 of 2013 to change the status of the recall to</p> <p>17 complete?</p> <p>18 A. Yes, I was.</p> <p>19 Q. Okay.</p> <p>20 A. Yes, I was.</p> <p>21 Q. Did you provide information to</p> <p>22 anybody that was communicated -- that went into</p> <p>23 that communication with the FDA requesting that</p> <p>24 the recall be determined to be completed?</p>
<p style="text-align: right;">Page 223</p> <p>1 - - -</p> <p>2 THE WITNESS: 62?</p> <p>3 MR. HAVERTY: 52.</p> <p>4 THE WITNESS: Okay.</p> <p>5 BY MR. HAVERTY:</p> <p>6 Q. First of all, who is Mark -- who</p> <p>7 is Chris Tupper, do you know?</p> <p>8 A. Chris Tupper, I'm not sure what</p> <p>9 his -- what his position exactly was, but he was</p> <p>10 in the -- I think it was maybe in the risk</p> <p>11 assessment department, and he communicated with</p> <p>12 the FDA.</p> <p>13 Q. Okay. If you can turn to the</p> <p>14 second page, all the way at the bottom.</p> <p>15 A. Okay.</p> <p>16 Q. This is an email from Chris</p> <p>17 Tupper to Thanh B. Tran at the FDA, and it begins</p> <p>18 on page 2 there and continues on to the next page</p> <p>19 where Mr. Tupper says to Mr. Thanh -- or Thanh, I</p> <p>20 don't know -- "The attached documents includes a</p> <p>21 description of the current status of our recall</p> <p>22 of the Paradigm insulin pump, the request for</p> <p>23 closure document and, the closure request form.</p> <p>24 The documents will be mailed to the District</p>	<p style="text-align: right;">Page 225</p> <p>1 A. I provided information to Chris</p> <p>2 Tupper on a regular basis when -- whenever he</p> <p>3 would ask for -- for it, but I don't know how he</p> <p>4 used that information in those communications.</p> <p>5 Q. Okay. And if you go back to page</p> <p>6 1.</p> <p>7 A. Yes.</p> <p>8 Q. All right. In the middle of the</p> <p>9 page there, there is an email from Mr. Thanh -- I</p> <p>10 assume it's Mr., I don't want to be -- make any</p> <p>11 assumptions, but to Chris Tupper dated</p> <p>12 January 31, 2014, about six weeks after the</p> <p>13 initial request. And Mr. Thanh writes, "Hi</p> <p>14 Chris, the Center For Device and Radiological</p> <p>15 Health does not concur with the termination of</p> <p>16 this recall due to:</p> <p>17 "1. In Medtronic's CAPA, the</p> <p>18 firm indicated that it was attempting to find a</p> <p>19 replacement membrane for the infusion sets. The</p> <p>20 firm appears to still be in the process of</p> <p>21 performing this action. The firm has not</p> <p>22 provided any updated information to verify that a</p> <p>23 new membrane was acquired, validated, and</p> <p>24 implemented. Without this information, it cannot</p>

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<p style="text-align: center;">Page 226</p> <p>1 be confirmed that the firm has adequately 2 mitigated the risk to health caused by this 3 issue."</p> <p>4 Do you -- were you aware of that 5 email response or that response from the FDA to 6 Mr. Tupper's request for -- to have the recall 7 deemed complete?</p> <p>8 A. Yes, I was.</p> <p>9 Q. Okay. And then Mr. Tupper 10 responds about a week later saying, "Hi Thanh, 11 This CAPA is currently in the 'action' phase. 12 Replacement membrane materials have been 13 identified and are being tested, validated and 14 qualified on the product level. The 'action' 15 phase is planned to be completed by March 2015. 16 Upon successful completion of the 'action' phase, 17 a 510(k) submission to FDA may be required prior 18 to the implementation of the replacement membrane 19 material. If no FDA submission is required, the 20 new material will be implemented into production 21 at the end of the 'action' phase; in case a new 22 510(k) is required, the implementation will 23 immediately follow the FDA clearance (planned for 24 July of 2015)."</p>	<p>1 Q. At that point, is it fair to say 2 that you were only focused on Versapor as your 3 material, replacement material?</p> <p>4 A. Yes.</p> <p>5 Q. If you could look at Exhibit 33, 6 please.</p> <p>7 A. 33?</p> <p>8 Q. 33, yeah.</p> <p>9 - - -</p> <p>10 (Deposition Exhibit No. AA-33, 11 PowerPoint, "February CAPA Review FEB 12 12 Status," Bates stamped MDT-BRACP-0054350 13 through MDT-BRACP-0054366, was marked for 14 identification.)</p> <p>15 - - -</p> <p>16 THE WITNESS: Okay.</p> <p>17 BY MR. HAVERTY:</p> <p>18 Q. This is a PowerPoint slide deck 19 entitled "February CAPA Review February 12 20 Status, Insulin Delivery by Norma Ojeda."</p> <p>21 And we've already established 22 that Ms. Ojeda was your supervisor. Correct?</p> <p>23 A. She was at some point. At this 24 point she may have moved on, but I don't</p>
<p style="text-align: center;">Page 227</p> <p>1 At that point in February of 2 2014, were you in the process of testing, 3 validating and qualifying a replacement membrane 4 material on the product level at that point?</p> <p>5 A. Again, I don't remember exactly 6 at which point of the process we were at that 7 time frame without looking at documents.</p> <p>8 Q. Okay. Well, if we go back to 9 Exhibit 2, we note that on page 8, which is 10 the -- it indicates that the validation was 11 expected to take place in May of 2014, and the 12 design review was due in April of 2014. Correct?</p> <p>13 A. Correct.</p> <p>14 Q. So what was the action phase? 15 The action phase is what? The testing and 16 validation of the product?</p> <p>17 A. Among other things.</p> <p>18 Q. Okay. What else is included in 19 the action phase?</p> <p>20 A. Identification and then testing 21 and validation, procurement, recommendation 22 packages. That's the most involved --</p> <p>23 Q. Okay.</p> <p>24 A. -- phase of all the CAPA.</p>	<p>1 remember.</p> <p>2 Q. And I wanted to ask you that 3 question.</p> <p>4 It doesn't really tell you what 5 year this is. It just says "February 12 Status."</p> <p>6 Are you able to tell when this 7 would have been referencing?</p> <p>8 A. Not without looking at more 9 documentation inside.</p> <p>10 Q. Okay all right. Well, if you 11 look at the second page, it has six items on the 12 agenda. Right?</p> <p>13 A. Right.</p> <p>14 Q. So the first one is "Bergquist," 15 B-E-R-G-Q-U-I-S-T, "on Donatelle."</p> <p>16 What's that referring to, do you 17 know?</p> <p>18 A. Well, it's a CAPA to replace a 19 part on a pump.</p> <p>20 Q. Okay. What pump was it looking 21 to replace?</p> <p>22 A. I don't know exactly, but it was 23 a Paradigm pump. I don't know if it was model 24 specific or not.</p>

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<p style="text-align: center;">Page 230</p> <p>1 Q. Then the next one is the "7xx 2 Phillips."</p> <p>3 What is that referring to?</p> <p>4 A. Phillips is a supplier that 5 provides cases for the pumps, so -- and 7 refers 6 to the series. So there was some work going on 7 there.</p> <p>8 Q. Okay. And then the next one is 9 "5xx Phillips."</p> <p>10 Is that related to the 7xx above 11 it, just a different pump size?</p> <p>12 A. Yes, yes.</p> <p>13 Q. All right. And then the next one 14 is the "A33 Motor Support Phase II."</p> <p>15 What is that referring to?</p> <p>16 A. That was, if I remember 17 correctly, a redesign for the motor support disc 18 for the motor support cap in the pump housing.</p> <p>19 Q. And what was the issue with the 20 motor support cap?</p> <p>21 A. It would occasionally become 22 loose and fall out of the pump.</p> <p>23 Q. And what was the hazard, if any, 24 related to that?</p>	<p style="text-align: center;">Page 232</p> <p>1 membrane material replacement project. Right?</p> <p>2 A. Correct.</p> <p>3 Q. So it looks like as of July of 4 2013, you had completed the milestone of 5 procuring samples. Correct?</p> <p>6 A. Right.</p> <p>7 Q. And then it says, the next step 8 was to "Execute initial testing (functional, 9 environment, manufacturing, human, etc.)," as of 10 January 15, 2014. Correct?</p> <p>11 A. Correct.</p> <p>12 Q. And then if you go all the way 13 over to the "Comments," it indicates as of 14 January 15th of 2014, "All testing completed 15 resulting in 3 materials left for production 16 consideration."</p> <p>17 And those were the three 18 materials that we talked about, the PM22S, the 19 Supor and the Versapor. Correct?</p> <p>20 A. Correct.</p> <p>21 Q. And then the next milestone is 22 "Update documentation (Specifications and 23 Drawings) and procure material for validation." 24 That was -- had a due date of February 10th of</p>
<p style="text-align: center;">Page 231</p> <p>1 A. The hazard was, if I remember 2 correctly, if a patient tries to push it back in, 3 it could initiate an uncontrolled delivery of 4 insulin.</p> <p>5 Q. And the next one is the "Prime 6 Fill Anomaly."</p> <p>7 So we know that this would have 8 had to have come in the February after the 9 prime/fill anomaly was detected. Correct?</p> <p>10 A. Correct.</p> <p>11 Q. You just don't know -- you can't 12 tell just looking at it whether it was February 13 of 2014 or February of 2015. Right?</p> <p>14 A. I cannot really.</p> <p>15 Q. If you go to the page -- and skip 16 over -- and by the way, those -- those six bullet 17 points are referring to different CAPAs that were 18 open. Correct?</p> <p>19 A. Correct, yes.</p> <p>20 Q. Okay. If you go to the page 21 that's marked last three numbers 364.</p> <p>22 A. Okay.</p> <p>23 Q. And this is a slide deck -- or 24 slide pertaining to your CAPA for the P-cap</p>	<p style="text-align: center;">Page 233</p> <p>1 2014. And at that -- as of this presentation, 2 the status was moved to March 28th of 2014. 3 Right?</p> <p>4 A. Correct.</p> <p>5 Q. And then it has -- the "Comments" 6 are "Membrane Spec is in Doc Control."</p> <p>7 What does that mean?</p> <p>8 A. That means -- so there is a 9 document we call materials specification that 10 needed to be updated to create new part numbers 11 for these new three selected membranes, part 12 numbers specific to Medtronic. It's a necessary 13 step in the process like this.</p> <p>14 Q. So that it's unique to that 15 particular part number. Correct?</p> <p>16 A. Correct. Yes.</p> <p>17 Q. And that would -- it would have 18 the part number, and it would have all of the 19 specifications that are associated with that 20 unique part number. Correct?</p> <p>21 A. That is correct.</p> <p>22 Q. All right. So does that mean 23 that as of March 28th, you expected to have at 24 least the wet flow spec completed at that point</p>

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<p>1 if you hadn't already?</p> <p>2 A. Not necessarily corrected --</p> <p>3 connected events. And could have been done</p> <p>4 internal, but I don't remember exactly the timing</p> <p>5 again.</p> <p>6 Q. Would the wet flow spec have been</p> <p>7 part of the membrane spec?</p> <p>8 A. No, no.</p> <p>9 Q. Okay. All right. So what kind</p> <p>10 of specifications would be part of the membrane</p> <p>11 spec that was in document control at that point?</p> <p>12 A. Okay. So membrane spec intent is</p> <p>13 to document -- document specifications of unique</p> <p>14 materials so it can be procured.</p> <p>15 Q. Okay. So the dimensions, those</p> <p>16 types of things. Right?</p> <p>17 A. It is basically a drawing for</p> <p>18 something that's purchased off shelf, that is not</p> <p>19 made specifically for Medtronic or not customized</p> <p>20 significantly to Medtronic.</p> <p>21 Q. Got it. Okay. Then the next</p> <p>22 milestone listed is the "Validate 2 materials on</p> <p>23 CAM 5."</p> <p>24 And that has a due date -- had a</p>	<p>1 Q. Got it.</p> <p>2 A. It will make it easier.</p> <p>3 Q. Okay. So that was planned to be</p> <p>4 done sometime in May, be completed as of May of</p> <p>5 2014. Correct?</p> <p>6 A. At this point in time, this was</p> <p>7 the plan, yes.</p> <p>8 Q. Okay. And then at this point,</p> <p>9 the next one is "Qualify new material on the</p> <p>10 product level." And its due date was December</p> <p>11 10th of 2014.</p> <p>12 That was pushed back</p> <p>13 substantially from the original date of April</p> <p>14 28th of 2015. Correct?</p> <p>15 A. Correct.</p> <p>16 Q. Do you know why that was pushed</p> <p>17 back?</p> <p>18 A. I don't remember exactly why, but</p> <p>19 there was a number of factors that caused delays.</p> <p>20 Q. Can you remember what some of</p> <p>21 them were?</p> <p>22 A. In documentation processing and</p> <p>23 procurement process and sometimes testing</p> <p>24 process, all of those accumulated to the -- to</p>
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<p>1 due date of May 14th -- or May 15th of 2014.</p> <p>2 And I assume that means since</p> <p>3 there's no status date, that it was expected to</p> <p>4 be on schedule?</p> <p>5 A. It's -- at this point, it's on</p> <p>6 schedule, but it hasn't started.</p> <p>7 Q. Okay. And what is "CAM 5 will be</p> <p>8 used for initial validation"? What does that</p> <p>9 mean?</p> <p>10 A. So "CAM" stands for cap</p> <p>11 acceptably machine. We operate three of them.</p> <p>12 They're named CAM 3, CAM 4 and CAM 5. At this</p> <p>13 point of time, CAM 3 and CAM 4 are located at</p> <p>14 Unomedical's facility in Denmark and are</p> <p>15 production qualified machines and running</p> <p>16 production almost 100 percent of the time.</p> <p>17 CAM 5 is the newest machine.</p> <p>18 They're all identical. CAM 5 is the newest</p> <p>19 machine, and it's housed at our other supplier</p> <p>20 called TECH Group in Phoenix, Arizona, and it's</p> <p>21 not qualified for production at that point.</p> <p>22 So the decision was to use that</p> <p>23 machine for validation due to its not being busy</p> <p>24 with production and proximity to Medtronic.</p>	<p>1 the major delay.</p> <p>2 Q. Okay. And then the -- at that</p> <p>3 point, the submission receipt was -- let me go</p> <p>4 back before I forget.</p> <p>5 When we talk about qualifying the</p> <p>6 new material on the product level, the "Comments"</p> <p>7 say, "Aging data is being reviewed. Major time</p> <p>8 contributor."</p> <p>9 What does that mean?</p> <p>10 A. Our infusion sets marketed by us,</p> <p>11 made by Unomedical, marketed by us, have a shelf</p> <p>12 life of three years, basically meaning that unit</p> <p>13 can be stored for three years while remaining</p> <p>14 functional and, most importantly, sterile.</p> <p>15 Whenever there is a major</p> <p>16 material change like we're talking about on the</p> <p>17 product like that, we need to prove that that new</p> <p>18 material will keep sterile and functional all the</p> <p>19 way up to the end of the duration of the shelf</p> <p>20 life, so we need to test it as such. Usually for</p> <p>21 the reasons of expediency, this testing is</p> <p>22 performed via so-called accelerated aging, where</p> <p>23 material is stored at elevated temperature and</p> <p>24 sometimes pressure and humidity to simulate</p>

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<p style="text-align: right;">Page 238</p> <p>1 aging.</p> <p>2 For example, at the -- at the 3 accelerated rate, one year of aging equals to 50 4 or 52 days in the environmental chamber. So to 5 simulate -- just to simulate three years' worth 6 of aging test, we needed close to six months of 7 time.</p> <p>8 Q. Okay. The next action item is 9 "Submission Receipt." That was expected for 10 August 19th of 2015. And it says it's "Under 11 review. Submission may not be required."</p> <p>12 Meaning that you might not have 13 to get the FDA's approval for that?</p> <p>14 A. Correct. At this point we are 15 not sure whether it -- we need to submit it to 16 FDA for approval or we can utilize the material 17 without such approval.</p> <p>18 Q. What determining factors were 19 there about whether or not it would require FDA 20 approval or not?</p> <p>21 A. I can't answer that question. 22 That would be a question for regulatory affairs.</p> <p>23 Q. Okay. And then the next action 24 item, milestone, was a "Closing Memo" expected in</p>	<p style="text-align: right;">Page 240</p> <p>1 A. We were, to reduce the risk of 2 one not passing and then not having to start 3 over.</p> <p>4 Q. Okay. What was the other one 5 that you were working on simultaneously?</p> <p>6 A. So it was Versapor 450R and the 7 PM22S from Porex.</p> <p>8 Q. When did you make the decision to 9 work on both of them simultaneously?</p> <p>10 A. I don't remember exactly when.</p> <p>11 Q. If you could look at Exhibit 12 A34 -- or Exhibit 34, please.</p> <p>13 - - -</p> <p>14 (Deposition Exhibit No. AA-34, 15 Engineering Reports, ER14-9258 Version A, 16 04/25/2014, Bates stamped 17 MDT-BRACP-0054857 through 18 MDT-BRACP-0054865, was marked for 19 identification.)</p> <p>20 - - -</p> <p>21 THE WITNESS: Uh-huh. 22 BY MR. HAVERTY:</p> <p>23 Q. Okay. 24 A. Okay.</p>
<p style="text-align: right;">Page 239</p> <p>1 September of 2015.</p> <p>2 That would be when you would 3 expect to close out the CAPA?</p> <p>4 A. Yes, that's correct.</p> <p>5 Q. All right. If you could turn to 6 the next page, please. This has a "P-Cap 7 Update."</p> <p>8 And I think you told us that the 9 Versapor that you were working with in 2014 you 10 were focused on was from Pall. Right?</p> <p>11 A. Correct.</p> <p>12 Q. And this one, on this slide, it 13 talks "About actions due Last Week. Receive 14 material from Porex." And material was shipped 15 on February 24th of '14.</p> <p>16 What is it that you were getting 17 from Porex?</p> <p>18 A. Material for production 19 validation.</p> <p>20 Q. Okay. So it was other than 21 Versapor?</p> <p>22 A. Correct.</p> <p>23 Q. So were you working on two 24 membrane materials simultaneously?</p>	<p style="text-align: right;">Page 241</p> <p>1 Q. And this is an engineering report 2 for P-cap membrane. The design verification 3 testing of P-caps with the Versapor 450R, and 4 it's dated April 25th of 2014.</p> <p>5 What is this report about?</p> <p>6 A. This report summarizes the 7 results of the testing performed on P-cap 8 assemblies with Versapor 450R material in them 9 manufactured by CAM 5 machine at Tech Group.</p> <p>10 Q. Did you have -- did you prepare a 11 similar engineering report around this time for 12 the Porex product?</p> <p>13 A. No. Porex was not -- to the best 14 of my knowledge, Porex was not done at the same 15 time yet.</p> <p>16 Q. Okay. Do you know why?</p> <p>17 A. No, I don't, but you cannot do 18 two materials at the same time. One needs to 19 take natural priority over the other.</p> <p>20 Q. Okay. And if you turn to page 8. 21 Okay.</p> <p>22 In your "Conclusions," you wrote, 23 "It is a conclusion of this report that Versapor 24 450R membrane...is a suitable replacement for the</p>

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<p style="text-align: center;">Page 242</p> <p>1 currently used membrane to be used in production 2 of the PCAP connector assembly. Moreover, the 3 testing captured in this report proved that the 4 ultrasonic welding process developed by the 5 supplier for the Versapor 450R membrane may be 6 used in production.</p> <p>7 "Although introduction of insulin 8 to the surface of the membrane reduces the flow 9 characteristics of the material, the membrane 10 remains gas permeable and demonstrated the air 11 flow that is higher than a required minimum of 12 5 SCCM."</p> <p>13 So this engineering testing, was 14 this considered -- was this part of the 15 validation?</p> <p>16 A. It's a part of verification, yes.</p> <p>17 Q. Okay. So at least as far as your 18 engineering testing in April of 2014, the 19 Versapor 450 was suitable for membrane material. 20 Correct?</p> <p>21 A. Correct.</p> <p>22 Q. And what was the next step that 23 was planned with the Versapor as of April of 24 2014?</p>	<p style="text-align: center;">Page 244</p> <p>1 requirements for us. And that test -- initial 2 testing was successful. And it was 3 commercially -- it commercially made sense as 4 well.</p> <p>5 Q. If you could look at Exhibit 35, 6 please.</p> <p>7 - - -</p> <p>8 (Deposition Exhibit No. AA-35, 9 PowerPoint, "Replacement Membrane for 10 PCAP Assembly CAPA QIR 13-006 Design 11 Review May 9, 2014," Bates stamped 12 MDT-BRACP-0054546 through 13 MDT-BRACP-0054423, was marked for 14 identification.)</p> <p>15 - - -</p> <p>16 THE WITNESS: Okay.</p> <p>17 BY MR. HAVERTY:</p> <p>18 Q. This is another PowerPoint slide 19 deck entitled "Replacement Membrane for PCAP 20 Assembly Design Review May 9, 2014." 21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Was this the design review 24 that you were talking about back in the action</p>
<p style="text-align: center;">Page 243</p> <p>1 A. The next steps were to validate 2 the same -- to -- to repeat the same validation 3 testing for CAM 3 and CAM 4 at Unomedical 4 followed by the production level validation.</p> <p>5 Q. Okay. Were you also at that same 6 time anticipating putting the Porex material 7 through the same process?</p> <p>8 A. Yes, but not at this time, at a 9 later date.</p> <p>10 Q. Were you holding that in reserve 11 in case the Versapor didn't work out?</p> <p>12 A. Not only that, it was a 13 constraint -- constraint on the resources and 14 other factors.</p> <p>15 Q. Okay. So let me understand this 16 part about it.</p> <p>17 Why was it that initially you 18 selected the Versapor as primary over the Porex 19 product?</p> <p>20 A. Because it was made by the same 21 manufacturer and same supplier to us, so that 22 relationship was already established and the 23 supplier was qualified. It seemed to -- it 24 seemed promising to fulfill the design</p>	<p style="text-align: center;">Page 245</p> <p>1 plan in the CAPA?</p> <p>2 A. Yes. Yes, that is correct?</p> <p>3 Q. Okay. Did you participate -- did 4 you participate in this design review?</p> <p>5 A. I conducted this design review.</p> <p>6 Q. Okay. If you look at the second 7 page --</p> <p>8 A. Yes.</p> <p>9 Q. -- you talk about 5 membranes 10 were initially selected, 3 were chosen for 11 detailed evaluation, and then you note, "1 was 12 selected for production validation based on test 13 results," the "VERSAPOR 450R membrane 14 manufactured by PALL." Right?</p> <p>15 A. Correct.</p> <p>16 Q. Okay. And you talk -- and the 17 next thing you talk about is the specification 18 for how much fluid may be deposited on the 19 membrane based upon that human factors testing. 20 Correct?</p> <p>21 A. Correct.</p> <p>22 Q. And then if you go to the next 23 page, you describe all the steps that have been 24 taken up to this point as of May of 2014.</p>

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1 Correct? 2 A. Correct. 3 Q. And if you go to the next page, 4 so you talk about the validation and 5 qualification plan. And you talk about the 6 testing on the CAM 5 machine. Right? 7 A. Correct. 8 Q. And then underneath that you have 9 "CAM 3 and CAM 4" at "UNO." 10 Had this testing been done at 11 Unomedical at this point, or was it anticipated? 12 A. It's anticipated. 13 Q. Do you have any idea when it was 14 anticipated to be done? 15 A. No, I don't remember exactly. 16 Q. Okay. At this point, as of May 17 of 2014, were you still on target to get the 18 closing memo done by September of 2015, do you 19 know? 20 A. I don't remember. 21 Q. But based upon the information 22 that you have, though, as of May of 2014, did 23 it -- does it look like you were on target to 24 close out the CAPA as of September of 2015?	Page 246 1 July of 2014, it was noted that "A new membrane 2 material, Versapor 450R, has been identified." 3 "Uno-Medical and TECH Group are in the process of 4 validating the new membrane on the current 5 production machines." 6 So do you take from that that 7 Unomedical was in the process of validating the 8 material on the CAM 3 and CAM 4 machines? 9 MS. MARTINEZ: Objection to form. 10 THE WITNESS: That is correct. 11 BY MR. HAVERTY: 12 Q. And then it goes on, it says, "At 13 the same" -- "at the same time, UNO discovered 14 inconsistencies in the Ultrasonic Welding process 15 and suspended PQs to...work" for -- "further work 16 on Process development." 17 What is that referring to? 18 A. That's referring to that during 19 the validation runs -- or actually, PQ run is a 20 mimic of a production run. They discovered some 21 challenges in processing of this material through 22 CAM machines and stopped the validation to go 23 back and look one more time at their processes 24 and try to make it work.
Page 247 1 A. It did. 2 Q. If you could look at Exhibit 36, 3 please. 4 - - - 5 (Deposition Exhibit No. AA-36, 6 Email chain, top one dated July 08, 2014, 7 Bates stamped MDT-BRACP-005460 through 8 MDT-BRACP-005462, was marked for 9 identification.) 10 - - - 11 BY MR. HAVERTY: 12 Q. Okay. This is an email dated 13 July 8, 2014 from you to Hubert Yeung regarding 14 the CAPA status. 15 Do you see that? 16 A. Yes. 17 Q. And you note, "I added a few 18 words about TECH group. I hope this still 19 works." 20 What was it you were trying to 21 do? 22 A. I don't remember exactly 23 clarification on what we were doing at Tech. 24 Q. Okay. So as of July of 2014,	Page 249 1 Q. The PQ refers to product 2 qualification. Correct? 3 A. Production qualification. 4 Q. Excuse me. And what was -- what 5 were the inconsistencies that were found? 6 A. There were voids in the materials 7 and inconsistencies in the welding process that 8 resulted in leakage. 9 Q. What was the understanding, if 10 there was any, about how these inconsistencies 11 were occurring in the manufacturing process? 12 A. Can you -- can you ask me again, 13 please? I wasn't clear. 14 Q. Yeah. We're all getting tired 15 here. Right? 16 What were the inconsistencies 17 that were -- that were being -- excuse me. 18 What was hypothesized about why 19 these inconsistencies were occurring? Was it 20 something to do with the manufacturing process? 21 Was it something to do with the material, or was 22 it something to do with both? 23 A. So at -- 24 MS. MARTINEZ: Object to form.

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<p style="text-align: right;">Page 250</p> <p>1 THE WITNESS: So at this point, 2 it's both.</p> <p>3 BY MR. HAVERTY:</p> <p>4 Q. Okay. But you didn't notice 5 these inconsistencies in the validation on the 6 CAM 5 equipment. Correct?</p> <p>7 A. That is correct.</p> <p>8 Q. So were -- was anybody able to 9 have -- come to an understanding about why the 10 CAM 5 machine could produce the material 11 successfully but the CAM 3 and CAM 4 machines 12 were having difficulty with inconsistent quality 13 or inconsistent results?</p> <p>14 MS. MARTINEZ: Object to the 15 form.</p> <p>16 THE WITNESS: It was attributed 17 to volume runs. So it was very short 18 runs at CAM 5, and we ran significantly 19 more parts at CAM 3 and CAM 4. And then 20 Unomedical is much more experienced with 21 running these machines than anybody else 22 in the world today. In fact, they 23 possess now all three machines. And they 24 didn't feel comfortable seeing what they</p>	<p style="text-align: right;">Page 252</p> <p>1 being used to manufacture your proprietary cap? 2 A. With --</p> <p>3 MS. MARTINEZ: Object to the 4 form.</p> <p>5 THE WITNESS: With material they 6 disclosed, yes. Material presented some 7 challenges, but process they wouldn't.</p> <p>8 BY MR. HAVERTY:</p> <p>9 Q. Okay. Do you know that even 10 though they wouldn't disclose it to you, do you 11 know how the processes on the CAM 3 and CAM 4 12 machines differed from the CAM 5 machine that you 13 were utilizing at Tech Group?</p> <p>14 A. No, I don't.</p> <p>15 Q. Okay. If you could look at -- 16 strike that.</p> <p>17 So when Unomedical decided to go 18 back and look at the different -- relook at it, 19 did the Porex material then come up to the fore 20 for validation?</p> <p>21 MS. MARTINEZ: Object to the 22 form.</p> <p>23 THE WITNESS: Not at that point, 24 but Porex came up back to validation when</p>
<p style="text-align: right;">Page 251</p> <p>1 saw with proceeding to production with 2 this, and they wanted to take it back to 3 reevaluate.</p> <p>4 BY MR. HAVERTY:</p> <p>5 Q. And was it -- did they deem it 6 was a material issue or was it a -- that it was 7 not suitable for the equipment?</p> <p>8 A. It was a combination of, and they 9 tried to modify it by trying different things on 10 the equipment and processing -- process 11 parameters, rather.</p> <p>12 Q. Okay. And you said they went 13 back and they were trying some different things. 14 What kind of different things did 15 they do?</p> <p>16 A. They would not disclose. Process 17 parameters with which they run the machines is 18 proprietary information to Uno.</p> <p>19 Q. Okay. But they're producing your 20 patented proprietary connector cap to your 21 specifications. Correct?</p> <p>22 A. Correct.</p> <p>23 Q. So why would they not disclose to 24 you what the issue was with the material that was</p>	<p style="text-align: right;">Page 253</p> <p>1 it was determined by everybody that 450R, 2 Versapor 450R, will be very challenging 3 in a high-volume manufacturing 4 environment.</p> <p>5 BY MR. HAVERTY:</p> <p>6 Q. So do you know when that decision 7 was made?</p> <p>8 A. No. I don't remember exactly.</p> <p>9 Q. Well, do you recall whether it 10 was in the summer of 2014 when we note that issue 11 in that email, or was it later, like in the fall, 12 winter?</p> <p>13 A. Somewhere in that time frame, 14 somewhere around fall of 2014.</p> <p>15 Q. Okay. If you could look at 16 Exhibit 37, please.</p> <p>17 - - -</p> <p>18 (Deposition Exhibit No. AA-37, 19 Email chain, top one dated July 28, 2014, 20 Bates stamped MDT-BRACP-0051355 through 21 MDT-BRACP-0051357, was marked for 22 identification.)</p> <p>23 - - -</p> <p>24 BY MR. HAVERTY:</p>

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<p style="text-align: right;">Page 254</p> <p>1 Q. Do you have that?</p> <p>2 A. Yes, I do.</p> <p>3 Q. Okay. This is an email chain.</p> <p>4 The top one on page 1 is from Yu Zhao to, among</p> <p>5 other people, you dated July 28th of 2014. And</p> <p>6 in it, it appears to indicate that the FDA has</p> <p>7 expressed its belief that a 510(k) submission</p> <p>8 would be necessary for the new material.</p> <p>9 Correct?</p> <p>10 A. Correct.</p> <p>11 Q. Okay. So this was at the time</p> <p>12 when you were sort of revisiting the Versapor</p> <p>13 material.</p> <p>14 Were you looking at the prospect</p> <p>15 of perhaps going back to the drawing board on</p> <p>16 these materials?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. Did you have any type of a</p> <p>19 timeline in your mind about how long it was going</p> <p>20 to take to go through this process again to</p> <p>21 qualify the Porex and get it ready for production</p> <p>22 development?</p> <p>23 A. Yes, I did.</p> <p>24 Q. Okay. What was your thinking at</p>	<p style="text-align: right;">Page 256</p> <p>1 Q. If you could take a look at</p> <p>2 Exhibit 40, please.</p> <p>3 - - -</p> <p>4 (Deposition Exhibit No. AA-40,</p> <p>5 Extension Request Form, 04/13/15, Bates</p> <p>6 stamped MDT-BRACP-029887 and</p> <p>7 MDT-BRACP-029888, was marked for</p> <p>8 identification.)</p> <p>9 - - -</p> <p>10 BY MR. HAVERTY:</p> <p>11 Q. And this is captioned as an</p> <p>12 "Extension Request Form."</p> <p>13 Is this requesting an extension</p> <p>14 for deadlines in the CAPA?</p> <p>15 A. Correct.</p> <p>16 Q. And this is indicated that a new</p> <p>17 due date is requested for 11/13/2015.</p> <p>18 And what does that due date</p> <p>19 require? Is that the estimated date of closing</p> <p>20 out the CAPA?</p> <p>21 A. No. That's just the estimated</p> <p>22 date to closing of an action phase of the CAPA.</p> <p>23 Q. And what's the next step after</p> <p>24 the action phase? Is it the actual production?</p>
<p style="text-align: right;">Page 255</p> <p>1 that time?</p> <p>2 A. As far as -- as far as how long</p> <p>3 is it going to take?</p> <p>4 Q. Yes.</p> <p>5 A. I don't remember exactly right</p> <p>6 now, but I would use the same methods and</p> <p>7 technique that I planned for originally with</p> <p>8 Versapor 450, because the workload would be the</p> <p>9 same exactly.</p> <p>10 Q. Okay. So it basically took you</p> <p>11 about a year with the Versapor from the time the</p> <p>12 material was selected and then shown to be</p> <p>13 acceptable till you got to the validation testing</p> <p>14 and the qualification by Unomedical. Correct?</p> <p>15 A. A little less than a year, but</p> <p>16 yes, about nine months.</p> <p>17 Q. So were you looking at -- in your</p> <p>18 mind, was it about the same process, that it</p> <p>19 would take you another nine months or more to get</p> <p>20 the new material validated?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. So you were looking at</p> <p>23 that point into 2015. Correct?</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 257</p> <p>1 A. From the CAPA standpoint, it's</p> <p>2 the collecting data that will be required in</p> <p>3 order to close the CAPA. It can be different</p> <p>4 things.</p> <p>5 Q. Okay. And you note in the</p> <p>6 request for extension that "The alternate</p> <p>7 material qualification has been completed,</p> <p>8 however due to various constraints and complexity</p> <p>9 of the testing it was not completed in projected</p> <p>10 time. Therefore, the FDA submission was not</p> <p>11 prepared in time that it was originally planned</p> <p>12 for. The FDA submission will be prepared and</p> <p>13 executed by UNO Medical. Medtronic will provide</p> <p>14 all test documentation so it can be included with</p> <p>15 submission."</p> <p>16 So is the FDA submission the date</p> <p>17 on which you're requesting the extension as the</p> <p>18 projected date? November --</p> <p>19 A. It's a projected date.</p> <p>20 Q. Okay. And then you justify it by</p> <p>21 "The submission preparation requires more time as</p> <p>22 the testing required consumed more time than</p> <p>23 originally planned and FDA Submission preparation</p> <p>24 requires coordination between Medtronic and UNO</p>

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<p style="text-align: right;">Page 258</p> <p>1 Medical. UNO Medical owns all regulatory 2 submissions on infusion set products."</p> <p>3 Was this extension of time 4 necessitated by the fact that the Versapor 5 material didn't work out and you had to go back 6 to the drawing board with the Porex?</p> <p>7 A. I don't remember without looking 8 at documentation exactly by this time what had -- 9 what had happened by the time I requested this 10 extension.</p> <p>11 Q. Okay. But you knew that sometime 12 in the fall -- summer/fall of 2014, that you were 13 going to have to go with the Porex material at 14 that point. Correct?</p> <p>15 A. That's correct.</p> <p>16 Q. And you were looking at another 17 nine months, as you said, probably to recomplete 18 the process. So that would have put you sometime 19 into the spring of 2015, correct, when you were 20 making this request?</p> <p>21 A. That is correct.</p> <p>22 Q. Okay. If you could take a look 23 at Exhibit 41. 24 - - -</p>	<p style="text-align: right;">Page 260</p> <p>1 high volume production environment. This 2 resulted in a decision to switch to an alternate 3 membrane material... This change has resulted in 4 a delay in the overall" projected "schedule to 5 complete material qualification activities and 6 implementation."</p> <p>7 And it now it looks like the new 8 due date being requested is about six months 9 later, of May of 2016. Correct?</p> <p>10 A. Correct.</p> <p>11 Q. So this was -- you were in the 12 process then of qualifying the Porex material?</p> <p>13 A. That is correct.</p> <p>14 Q. And the new due date that was 15 requested, 5/5 of'16, is that the projected 16 submission to the FDA?</p> <p>17 A. This is projected completion 18 date.</p> <p>19 Q. Okay. In your justification for 20 the extension, you note, "Although the failure 21 that may be caused by a temporarily blocked 22 venting membrane may be critical, the occurrence 23 still remains very low. In addition to the 24 rarity of the potential failure, instructions for</p>
<p style="text-align: right;">Page 259</p> <p>1 (Deposition Exhibit No. AA-41, 2 Extension Request Form, 10/26/15, Bates 3 stamped MDT-BRACP-029889 through 4 MDT-BRACP-029891, was marked for 5 identification.) 6 - - -</p> <p>7 BY MR. HAVERTY:</p> <p>8 Q. This is another CAPA extension 9 request dated October 26, '15, about six months 10 after the last one we saw. Right?</p> <p>11 A. Yes.</p> <p>12 Q. Then it goes on to say, the 13 reason for the extension is, "During the 14 execution of the action phase at our supplier 15 (Unomedical), the originally selected replacement 16 membrane material...was found to be difficult to 17 process in large quantities. This resulted in us 18 stopping the material validation activity at 19 Unomedical. Although the membrane material...had 20 already been qualified by the second P-CAP 21 assembly supplier (TECH Group), discussion with 22 both suppliers and our internal team determined 23 that due to manufacturability issues, the" 24 earlier "material would not be suitable for a</p>	<p style="text-align: right;">Page 261</p> <p>1 all Paradigm infusion sets have been updated with 2 warnings and special instructions pertaining to 3 the temporary block issue."</p> <p>4 Was it your understanding that 5 those warnings were the ones that we looked at 6 earlier that were in the IFUs?</p> <p>7 A. Correct, yes. I am understanding 8 that.</p> <p>9 Q. Okay.</p> <p>10 "There have been no new 11 observations of the blocked membrane since the 12 instruction update. There are no new product 13 safety risks in extending this CAPA."</p> <p>14 Where did you get the information 15 that there were "no new observations of the 16 blocked membrane since the instruction" 17 upgrade -- "update"?</p> <p>18 A. I don't remember exactly where, 19 but I would get this information generally from 20 our reporting department.</p> <p>21 Q. Okay. And you were aware that as 22 a result of this prime/fill anomaly 23 investigation, that there was a new code that was 24 entered into the system specifically dedicated to</p>

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<p style="text-align: right;">Page 262</p> <p>1 the blocked vent phenomenon. Correct?</p> <p>2 A. Correct. I was.</p> <p>3 Q. Okay. If you could take a look</p> <p>4 at Exhibit 43, please.</p> <p>5 - - -</p> <p>6 (Deposition Exhibit No. AA-43,</p> <p>7 Validation Summary Report for CAM 3,</p> <p>8 Bates stamped MDT-BRACP-029574 through</p> <p>9 MDT-BRACP-029578, was marked for</p> <p>10 identification.)</p> <p>11 - - -</p> <p>12 THE WITNESS: Okay.</p> <p>13 BY MR. HAVERTY:</p> <p>14 Q. This is a "Validation Summary</p> <p>15 Report for CAM 3" with new P-cap material --</p> <p>16 P-cap membrane material.</p> <p>17 Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. And there is something that</p> <p>20 struck me when I saw this report is that was this</p> <p>21 the validation that was supposed to be done by</p> <p>22 Unomedical?</p> <p>23 A. This is Unomedical, yes.</p> <p>24 Q. Yes. Because it's the CAM 3.</p>	<p style="text-align: right;">Page 264</p> <p>1 Q. When did you first start seeing</p> <p>2 ConvaTec logos on documentation from Unomedical?</p> <p>3 A. I don't remember.</p> <p>4 Q. In any event, this was the</p> <p>5 CAM 3 -- is this the production qualification</p> <p>6 report for the new membrane material?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And it's dated December</p> <p>9 16th of 2015. Correct?</p> <p>10 A. The initial signature, yes. But</p> <p>11 it wasn't approved until January 4th, I see.</p> <p>12 Q. Okay.</p> <p>13 A. Completely approved, yes.</p> <p>14 Q. Oh, I see what you're talking</p> <p>15 about there, in the middle there, quality</p> <p>16 assurance -- "Quality Engineering/Assurance"?</p> <p>17 A. Right.</p> <p>18 Q. And if you could -- just put that</p> <p>19 aside and look at Exhibit 44 as well.</p> <p>20 - - -</p> <p>21 (Deposition Exhibit No. AA-44,</p> <p>22 Validation Summary Report for CAM 4,</p> <p>23 Bates stamped MDT-BRACP-029767 through</p> <p>24 MDT-BRACP-029771, was marked for</p>
<p style="text-align: right;">Page 263</p> <p>1 Correct?</p> <p>2 A. Correct.</p> <p>3 Q. All the way up at the top there,</p> <p>4 right next to where it says "Validation Summary</p> <p>5 Report for CAM 3," it has the name ConvaTec and a</p> <p>6 logo there.</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. Who is ConvaTec?</p> <p>10 A. As far as I know, ConvaTec is a</p> <p>11 parent company to Unomedical.</p> <p>12 Q. Okay. Had you ever seen</p> <p>13 materials come by in a -- with a ConvaTec logo</p> <p>14 before dealing -- in your dealings with</p> <p>15 Unomedical?</p> <p>16 A. I'm sorry. Did I see materials</p> <p>17 you asked me?</p> <p>18 Q. Yeah. Have you ever seen -- have</p> <p>19 you ever seen that before, that logo on materials</p> <p>20 that you were dealing with Unomedical on?</p> <p>21 A. When you refer to materials, do</p> <p>22 you mean the product or documentation or both?</p> <p>23 Q. Documentation.</p> <p>24 A. Yes, I have.</p>	<p style="text-align: right;">Page 265</p> <p>1 identification.)</p> <p>2 - - -</p> <p>3 THE WITNESS: Okay.</p> <p>4 BY MR. HAVERTY:</p> <p>5 Q. Okay. And this is the same</p> <p>6 validation summary report but for the CAM 4</p> <p>7 machine. Correct?</p> <p>8 A. That is correct.</p> <p>9 Q. Why did you need to do a</p> <p>10 validation on both the CAM 3 and CAM 4 machines?</p> <p>11 A. That's a procedural requirement.</p> <p>12 Every equipment needs to be -- every piece of</p> <p>13 equipment needs to be validated separately.</p> <p>14 Q. Those machines, though, are</p> <p>15 identical, are they not?</p> <p>16 A. Yes. To the -- for the most</p> <p>17 part.</p> <p>18 Q. Okay. So this was testing that</p> <p>19 was done then sometime in December of 2015 with</p> <p>20 the new Porex material. Correct?</p> <p>21 A. Correct.</p> <p>22 Q. So you had been able to get</p> <p>23 through all of the testing and the manufacturing</p> <p>24 issues with the Porex material that you couldn't</p>

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<p>1 get with the Versapor. Correct?</p> <p>2 A. That is true, yes.</p> <p>3 Q. So at this point you were getting</p> <p>4 ready to put it together and submit it to the</p> <p>5 FDA. Correct?</p> <p>6 A. No.</p> <p>7 Q. Okay.</p> <p>8 A. No, not yet.</p> <p>9 Q. What was the next step?</p> <p>10 A. This next step would be</p> <p>11 qualification on the product level and also all</p> <p>12 the verification testing, including aging testing</p> <p>13 at Medtronic.</p> <p>14 Q. Okay. And how does aging testing</p> <p>15 take place? How is that done?</p> <p>16 A. Sample units are placed -- again,</p> <p>17 this is as we talked -- as we talked earlier,</p> <p>18 this is an accelerated aging test. Sample units</p> <p>19 are placed in the oven at the determined</p> <p>20 parameters, temperature, usually temperature,</p> <p>21 sometimes pressure or humidity. And they're kept</p> <p>22 there for a determined -- predetermined period of</p> <p>23 time, after which they're pulled out and</p> <p>24 subjected to functional testing.</p>	<p>1 BY MR. HAVERTY:</p> <p>2 Q. All right. This is -- the top</p> <p>3 one is an email from Henrik Nielsen to you, among</p> <p>4 others, dated March 4th of -- no. I guess, is</p> <p>5 this April or March 4th, because I know in Europe</p> <p>6 they do it backwards. They do it differently.</p> <p>7 MS. MARTINEZ: Yes.</p> <p>8 BY MR. HAVERTY:</p> <p>9 Q. Is it --</p> <p>10 A. This is March. If you look at</p> <p>11 the second email, it says 3rd March --</p> <p>12 Q. March.</p> <p>13 A. -- in Danish.</p> <p>14 Q. Got it. So it's March 4th of</p> <p>15 2016 indicating that the 510(k) submission were</p> <p>16 sent to the FDA as of that date. Correct?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. So at that point</p> <p>19 everything had been done and it was ready for the</p> <p>20 FDA's review. Correct?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. If you could look at</p> <p>23 Exhibit 47, please.</p> <p>24 - - -</p>
<p>1 Q. Okay. How long does that</p> <p>2 typically take for this -- for that material?</p> <p>3 A. In this particular case, it took</p> <p>4 about 50 or 52 days to represent each year of</p> <p>5 aging.</p> <p>6 Q. 52 days?</p> <p>7 A. 50 or 52 days.</p> <p>8 Q. Okay. Once the aging was</p> <p>9 completed, would that be the last step before</p> <p>10 submitting to the FDA?</p> <p>11 A. After completion and release of a</p> <p>12 report summarizing the results of all the testing</p> <p>13 and providing that report to Unomedical, at that</p> <p>14 point it was in Unomedical's hands to submit.</p> <p>15 Q. Okay. If you could take a look</p> <p>16 at Exhibit 46, please.</p> <p>17 - - -</p> <p>18 (Deposition Exhibit No. AA-46,</p> <p>19 Email chain, top one dated 3/4/2016,</p> <p>20 Bates stamped MDT-BRACP-029773 and</p> <p>21 MDT-BRACP-029774, was marked for</p> <p>22 identification.)</p> <p>23 - - -</p> <p>24 THE WITNESS: Okay.</p>	<p>1 (Deposition Exhibit No. AA-47,</p> <p>2 Unomedical A/S Medtronic Subcutaneous</p> <p>3 Infusion Sets with P-Cap Premarket</p> <p>4 Notification Special 510(k), Bates</p> <p>5 stamped MDT-BRACP-028752 through</p> <p>6 MDT-BRACP-028857, was marked for</p> <p>7 identification.)</p> <p>8 - - -</p> <p>9 BY MR. HAVERTY:</p> <p>10 Q. You got that?</p> <p>11 A. I got it.</p> <p>12 Q. Okay. And this is a copy of the</p> <p>13 original initial 510(k) submission to the FDA for</p> <p>14 the Medtronic subcutaneous infusion sets with</p> <p>15 P-cap premarket notification special 510(k).</p> <p>16 Correct?</p> <p>17 A. I never seen this document</p> <p>18 before, but looks like it.</p> <p>19 Q. Okay. Would you typically have</p> <p>20 seen the 510(k) submission?</p> <p>21 A. No.</p> <p>22 Q. Why not?</p> <p>23 A. To be honest, I don't know -- I</p> <p>24 don't know how to answer to this question, but</p>

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<p style="text-align: center;">Page 270</p> <p>1 it's not a part of my responsibility, so I leave 2 it with my regulatory affairs partners to take 3 care of this.</p> <p>4 Q. Okay. If you could turn to 5 page 4, page 4.</p> <p>6 A. Okay.</p> <p>7 Q. And this is a letter addressed to 8 the US Food and Drug Administration on, again, 9 ConvaTec letterhead. Correct?</p> <p>10 A. Correct.</p> <p>11 Q. Okay.</p> <p>12 MS. MARTINEZ: Object to form. BY MR. HAVERTY:</p> <p>14 Q. Okay. Well, would you agree with 15 me, Mr. Aleksandrovich, that at the top 16 right-hand side of the letter is a logo and 17 underneath of it is the name ConvaTec. Correct?</p> <p>18 A. Correct.</p> <p>19 Q. And it's dated March 1st of 2016. 20 Correct?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. If you look down at the 23 bottom there, where it says "Reason for Change." 24 Do you see that?</p>	<p style="text-align: center;">Page 272</p> <p>1 Q. And that was consistent with the 2 entire CAPA process that you followed from 2013 3 through 2016. Correct?</p> <p>4 A. Correct.</p> <p>5 Q. All right. If you could turn to 6 page -- the last three numbers are 759.</p> <p>7 A. Okay.</p> <p>8 Q. And in paragraph 1.9 there, it 9 lists company contacts. And over on the right, 10 one of the contacts is listed as a Lee Leichter, 11 president of P/L Biomedical in Fort Myers, 12 Florida.</p> <p>13 Do you know who Mr. Leichter is?</p> <p>14 A. I do.</p> <p>15 Q. Who is he?</p> <p>16 A. He is a person that represents 17 Unomedical or helps Unomedical in the affairs 18 with FDA.</p> <p>19 Q. Okay. And what is P/L 20 Biomedical?</p> <p>21 A. I'm not sure what P/L Biomedical 22 is.</p> <p>23 Q. Is he a consultant, to your 24 knowledge?</p>
<p style="text-align: center;">Page 271</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And this is represented to 3 the FDA, "This submission describes the change in 4 material made to the P-Cap membrane. This change 5 is a part of the corrective action commitments 6 made by Medtronic related to the Class I Field 7 Corrective Action."</p> <p>8 Did you -- do you recall that 9 Medtronic made corrective action commitments to 10 the FDA as a part of the Class I recall from June 11 of 2013?</p> <p>12 A. Yes. In the letter previously 13 discussed Jeff Hubauer made that commitment to 14 the FDA.</p> <p>15 Q. Okay. And then it says 16 "Medtronic communicated to FDA a short term and 17 long term plan of action as part of the recall, 18 where the immediate action taken was addition of 19 a warning to the infusion set IFUs and the longer 20 term action which was to source and implement a 21 replacement membrane that is able to remain gas 22 permeable with certain amount of liquid deposited 23 in the P-cap." Correct?</p> <p>24 A. Correct.</p>	<p style="text-align: center;">Page 273</p> <p>1 A. Yes, he is a consultant.</p> <p>2 Q. Okay. If you could go to page 3 765.</p> <p>4 A. Okay.</p> <p>5 Q. Paragraph 5.1. 5.1.1.</p> <p>6 A. Okay.</p> <p>7 Q. "Change Description. The only 8 change to the device was a change in the material 9 of the P-Cap membrane. The change in the 10 membrane material was a direct outcome of a 11 recall issued by Medtronic June 2013 during which 12 Medtronic committed to the FDA to source a new 13 membrane material to reduce the potential for the 14 membrane to become occluded when wet. The 15 current Membrane material, a Pall Emflon PTFE 16 Membrane that is laminated to non-woven polyester 17 support material, will be replaced with a Porex 18 100% PTFE material." Right?</p> <p>19 A. Right.</p> <p>20 Q. Now, what about the Porex? We 21 went back and we talked about when Mr. Grover did 22 the testing where you turned the PTFE layer of 23 the membrane inward and you still couldn't 24 maintain air flow.</p>

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<p style="text-align: right;">Page 274</p> <p>1 What was different about the 2 Porex material made of PTFE that would still 3 allow air flow, gas permeability? 4 A. Because Porex is nothing but 5 PTFE. There is no polyester layer, and it 6 doesn't matter which way Porex is attached to the 7 P-cap. It will remain hydrophobic, and it will 8 remain gas permeable.</p> <p>9 Q. Okay. But that's what I'm trying 10 to understand is, is that how come if you turn 11 the PTFE layer in on the Emflon material, the 12 PTFE layer still would not be gas permeable if it 13 got wet as Mr. Grover's testing showed?</p> <p>14 A. So if Emflon material is 15 inverted, then it will become gas impermeable 16 when liquid is introduced from the outside of the 17 pump.</p> <p>18 Q. From the outside. 19 But did they -- did you test air 20 flow by introducing liquid on the inside of the 21 cap with the inverted PTFE layer?</p> <p>22 A. I don't remember exactly how Ben 23 did this.</p> <p>24 Q. Okay. I'm just trying to</p>	<p style="text-align: right;">Page 276</p> <p>1 BY MR. HAVERTY: 2 Q. Okay. This looks like the 3 packaging of the infusion sets, does it not? It 4 indicates Med -- 5 A. This is -- this is a back page of 6 an IFU. 7 Q. Okay. And it indicates at the 8 top there, it has "Medtronic" and then underneath 9 of that it has a logo, it says, "Unomedical, A 10 ConvaTec Company." 11 Do you see that? 12 A. I do. 13 Q. Let's see. We saw that email 14 where you were informed that the 510(k) had been 15 submitted to the FDA in March of 2016. 16 But you said a copy of that was 17 not sent to you. Correct? 18 A. I did not say that. 19 Q. Okay. 20 A. I was not interested in a copy. 21 Q. Why were you not interested in a 22 copy? 23 A. Like I said, I will -- this is a 24 regulatory affairs document, and I don't think I</p>
<p style="text-align: right;">Page 275</p> <p>1 understand, because it seemed to me, the 2 impression that I got was that the purpose for 3 inverting it was to see if going with the PTFE 4 layer would be adequate to preserve the gas 5 permeability, and it didn't sound like that 6 worked?</p> <p>7 A. Again, I need to look at exactly 8 what Ben did with that experiment.</p> <p>9 Q. Okay. And in any event, it 10 indicates what the current material is, is Pall 11 Corporation, it's the Emflon PTFE membrane which 12 was going to be replaced by the Porex porous PTFE 13 materials. Correct?</p> <p>14 A. Correct.</p> <p>15 Q. Okay. By the way, if you could 16 turn to the page that ends in 805.</p> <p>17 A. 805? These are not numbered.</p> <p>18 MS. MARTINEZ: Look right here.</p> <p>19 - - -</p> <p>20 (A discussion off the record 21 occurred.)</p> <p>22 - - -</p> <p>23 THE WITNESS: Okay.</p>	<p style="text-align: right;">Page 277</p> <p>1 have any business in that document. I provided 2 all the information requested, and that's where 3 it stops.</p> <p>4 Q. Okay. And is today the first 5 time that you've ever seen this submission?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. Once the submission was 8 made to the FDA, did you not have any involvement 9 or follow-up on anything after that at all?</p> <p>10 A. I did.</p> <p>11 Q. What did you do?</p> <p>12 A. So the FDA responded with some 13 questions for -- and asked for additional 14 informations -- information on that submission, 15 and that's where I got involved. I helped 16 Unomedical to develop answers to those questions 17 that FDA provided.</p> <p>18 Q. If you could look at Exhibit 48, 19 please.</p> <p>20 - - -</p> <p>21 (Deposition Exhibit No. AA-48, 22 Deficiency List, Bates stamped 23 MDT-BRACP-028858 through 24 MDT-BRACP-028860, was marked for</p>

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<p style="text-align: right;">Page 278</p> <p>1 identification.) 2 - - - 3 THE WITNESS: I got it. 4 BY MR. HAVERTY: 5 Q. Is this the FDA deficiency list 6 that you helped Unomedical to respond to? 7 A. Yes. 8 Q. Okay. And I love this with the 9 FDA, they never seem to date anything. 10 A. Never noticed. 11 Q. Do you know when this deficiency 12 letter was generated? 13 A. No. I don't remember exactly 14 when. 15 Q. Okay. All right. Then if you 16 can look at Exhibit 49, please. 17 - - - 18 (Deposition Exhibit No. AA-49, 19 Extension Request Form, 04/13/16, Bates 20 stamped MDT-BRACP-029892 and 21 MDT-BRACP-029893, was marked for 22 identification.) 23 - - - 24 THE WITNESS: Okay.</p>	<p style="text-align: right;">Page 280</p> <p>1 Exhibit 50, please. 2 Oh, before you do that, looking 3 back at Exhibit 49, so it looks like the new 4 target date for completing the CAPA was November 5 18th of 2016. Correct? 6 A. Correct. 7 Q. Okay. If you could look at 8 Exhibit 50, please. 9 - - - 10 (Deposition Exhibit No. AA-50, 11 Porex FDA Questions Response, Bates 12 stamped MDT-BRACP-028861 through 13 MDT-BRACP-028889, was marked for 14 identification.) 15 - - - 16 BY MR. HAVERTY: 17 Q. If you can go through this just 18 real quickly and tell me which responses you 19 assisted Unomedical with, just by number. 20 A. Yeah. 11, 12 questions, yeah. 21 No, no. I remember that there 22 was 11 or 12 questions. I helped on some of 23 them. 24 It's not going to be an easy task</p>
<p style="text-align: right;">Page 279</p> <p>1 BY MR. HAVERTY: 2 Q. All right. This is another CAPA 3 extension request dated April 13th of 2016, 4 signed by you. Correct? 5 A. Correct. 6 Q. And you note that the reason for 7 the extension was "The special 510(k) submission 8 was prepared by and sent to FDA by Unomedical... 9 however it was rejected by the FDA. FDA 10 requested that the submission be converted to a 11 traditional 510(k) submission. Such submission 12 requires a review period of up to 90 days as 13 opposed to originally planned 30 days for the 14 special 510(k) submission. A resubmission will 15 be required thus further expanding the action 16 phase." 17 And then you note the 18 justification was because of the FDA's 19 requirement that the special 510(k) be 20 committed -- converted to a traditional 510(k). 21 Do you know what the reasons were 22 for the FDA requiring that? 23 A. No, I don't recall. 24 Q. Okay. If you could look at</p>	<p style="text-align: right;">Page 281</p> <p>1 to do this. 2 Q. Because they're kind of enmeshed? 3 A. They're meshed together, and the 4 wording that I provided may have been changed to 5 be more suitable for FDA submission. 6 Q. Okay. Did you do any additional 7 testing or any type of validation, or is it 8 simply responding with documentation or 9 explanations? 10 A. It's the latter. Yeah. There 11 was no additional testing required. 12 Q. Okay. 13 A. It was mostly clarification work. 14 Q. Okay. Do you remember how much 15 time you spent on this? 16 A. Probably back and forth, around 17 two weeks. 18 Q. And do you know when the -- when 19 this was submitted to the FDA? 20 A. No, I don't remember. 21 Q. Were you provided a copy of the 22 submission to the FDA? 23 A. I don't remember. 24 Q. If you could take a look at</p>

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1 Exhibit 51, please. 2 - - - 3 (Deposition Exhibit No. AA-51, 4 Letter dated August 10, 2016, Bates 5 stamped MDT-BRACP-028890 and 6 MDT-BRACP-028891, was marked for 7 identification.) 8 - - - 9 THE WITNESS: Okay. 10 BY MR. HAVERTY: 11 Q. And this is a letter -- the FDA 12 dated this one -- a letter dated August 10, 2016 13 from the FDA to Unomedical indicating that they 14 reviewed the 510(k) premarket notification and 15 found that the device was substantially 16 equivalent to legally marketed predicate devices 17 marketed in interstate commerce. 18 So this is basically the date of 19 the approval or the substantial equivalency 20 letter from the FDA. Correct? 21 A. Correct. 22 Q. So it was at this point that 23 Unomedical could begin production of the 24 materials contained in the new membrane.	Page 282 1 Q. I take it from your answer, do 2 you do that today? 3 A. Yes. Due to the -- due to the 4 systemic change that Medtronic has implemented. 5 Q. When did Medtronic implement this 6 systemic change? 7 A. In August of 2017, I believe. 8 Q. Do you know what it was -- 9 A. Or a little earlier. 10 Q. Do you know what it was that 11 prompted this systemic change? 12 A. It was just the modern 13 technology. We implemented a paper-free system. 14 Q. So at the time the FDA approved 15 this, you did not have in place the mechanisms by 16 which you could expedite getting into production. 17 Right? 18 A. We didn't. Correct. 19 Q. Okay. So you expected that that 20 could take another month or so? 21 A. Yeah. Yes. 22 Q. So we're talking about 23 mid-September at that point? 24 A. Somewhere -- something to that
Page 283 1 Correct? 2 A. No, not exactly, this is not last 3 point. There are a few steps to be taken before 4 that. 5 Q. Okay. What needed to be done at 6 that point? 7 A. It's -- it's a documentation 8 release from so-called prototype status to 9 production status. 10 Q. And what does that involve? 11 A. In this case, changing drawings 12 mostly and a few bill of -- bills of materials 13 and processing and engineering change order at 14 Medtronic. 15 Q. Okay. How long would that 16 process ordinarily be expected to take? 17 A. Normally three, four weeks. I 18 don't remember how long this one -- this exact 19 one took. 20 Q. Would you have begun that process 21 or at least put it in place in anticipation of 22 getting FDA approval so that you could move on to 23 production as expeditiously as possible? 24 A. Not back then.	Page 285 1 extent. 2 Q. It would have been at that point 3 that Unomedical would have been in a position to 4 begin production of the membranes, the P-caps? 5 A. No. 6 MS. MARTINEZ: Object to the 7 form. 8 THE WITNESS: No. 9 BY MR. HAVERTY: 10 Q. What would have to happen 11 before -- before that? 12 A. Medtronic providing complete set 13 of production release documentation to Unomedical 14 and I would assume a properly executed purchase 15 orders. 16 Q. Okay. How long do you think that 17 process would take? 18 MS. MARTINEZ: Object to the 19 form. 20 THE WITNESS: Which one? If you 21 can clarify, please. 22 BY MR. HAVERTY: 23 Q. Well, we've established that 24 there were certain documentation that would need

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<p>1 to be done and it would take about a month, so 2 we're into September now of 2016. Then you said 3 there were additional documentation that would 4 have to be done and purchase orders and all that. 5 How long would you expect that 6 process to take before Unomedical would be in a 7 position to begin manufacturing the new P-caps?</p> <p>8 A. Okay.</p> <p>9 MS. MARTINEZ: Object to the 10 form.</p> <p>11 THE WITNESS: So as far as 12 providing production documentation, 13 that's literally one email from me. I 14 cannot speak to the length that it takes 15 purchase orders to be executed. And then 16 upon that, Unomedical would be -- would 17 be free to procure new material, which 18 has its own lead time. And only then, 19 after receipt of said material, they can 20 start production.</p> <p>21 BY MR. HAVERTY:</p> <p>22 Q. And again, there were no 23 processes in place to expedite that process once 24 the FDA approval was achieved. Right?</p>	<p>1 BY MR. HAVERTY: 2 Q. Okay. If you go back to 3 Exhibit 2, please, and look on page 61. 4 A. I'm sorry, 61? 5 Q. 61. Yes. I think it's 61. 6 MS. MARTINEZ: 61? 7 MR. HAVERTY: 61. 8 THE WITNESS: Okay. Yes. 9 BY MR. HAVERTY: 10 Q. This is from the final CAPA 11 report, and it's under the "Result," it says. 12 And it says, "The Action Phase for this CAPA has 13 been completed as planned." 14 And by the way, it's dated 15 November 9th of 2016. Correct? 16 A. Correct. 17 Q. It says, "The Action Phase for 18 this CAPA has been completed as planned. Upon 19 identifying possible alternative materials that 20 could be suitable for replacement of the 21 currently used PCAP membrane material, those 22 possible alternatives were thoroughly tested. 23 Testing revealed that membrane material 24 manufactured by POREX in a clear choice for</p>
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<p>1 A. Not -- 2 MS. MARTINEZ: Object to the 3 form.</p> <p>4 THE WITNESS: Not to my 5 knowledge.</p> <p>6 BY MR. HAVERTY:</p> <p>7 Q. So everything was going to be 8 done in the normal, ordinary sort of bureaucratic 9 process that you would do for any other type of 10 procedure. Correct?</p> <p>11 MS. MARTINEZ: Object to form. 12 MR. MERRELL: Objection to form. 13 THE WITNESS: That is correct.</p> <p>14 BY MR. HAVERTY:</p> <p>15 Q. Given the hazard of the old 16 material, was there any sense of urgency in 17 getting the new material onto the market?</p> <p>18 MR. MERRELL: Objection to form. 19 MS. MARTINEZ: Object to the 20 form.</p> <p>21 THE WITNESS: There was no new 22 urgency introduced at this point after -- 23 after mitigating it with wordings and -- 24 and everything else that we've done.</p>	<p>1 replacement of the currently used PCAP material. 2 The membrane spec document and PCAP assembly 3 drawing...were up" and -- "were updated with 4 prototype versions of the Membrane material 5 itself...as well as PCAP assembly version 6 featuring new POREX material." 7 That was basically, you were just 8 describing that the CAPA phase of the project is 9 complete at that point. Correct? 10 A. Correct. 11 Q. If you go down to the last -- the 12 last paragraph on that, it says, "Upon successful 13 completion of all testing, the material change 14 was submitted to FDA for review and the approval 15 to implement new membrane material into 16 production was granted. All documentation was 17 updated to production status (...released on 18 10-10-16)." 19 Do you see that? 20 A. I do. 21 Q. That was -- that's ECO. That's 22 an engineering change order. Correct? 23 A. Correct. 24 Q. Is that the last step that's</p>

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<p style="text-align: right;">Page 290</p> <p>1 necessary for the manufacturer to begin the 2 manufacturing process?</p> <p>3 MS. MARTINEZ: Object to the 4 form.</p> <p>5 THE WITNESS: Yes. It's a 6 trigger for supplier to start executing.</p> <p>7 BY MR. HAVERTY:</p> <p>8 Q. Okay. And then it goes on, it 9 says, "and the supplier was notified to phase new 10 material into production as soon as the stock of 11 current material is depleted."</p> <p>12 Was that referring to the current 13 stock of Emflon material?</p> <p>14 A. That is correct.</p> <p>15 Q. So do I -- so it says, 16 "Production is scheduled to start January of 17 2017." Correct?</p> <p>18 A. Right.</p> <p>19 Q. So it was anticipated that from 20 at least October, if not from earlier than that, 21 until January of 2017, Unomedical was going to 22 continue to manufacture infusion sets with the 23 connector cap with the Emflon membrane still in 24 it. Correct?</p>	<p style="text-align: right;">Page 292</p> <p>1 Q. Okay. Did anybody express any 2 dissent with that, that they should get the Porex 3 material into production as soon as possible?</p> <p>4 A. No, not that I remember.</p> <p>5 Q. Okay. And in fact, correct me if 6 I'm wrong, but the infusion sets containing the 7 new Porex material didn't actually come to market 8 until about April of 2017. Correct?</p> <p>9 A. That is correct.</p> <p>10 Q. When did production of those sets 11 actually begin?</p> <p>12 A. I cannot answer that question, 13 because that is internal Unomedical scheduling.</p> <p>14 Q. Okay. So you have no idea when 15 it happened. Right?</p> <p>16 A. That is correct.</p> <p>17 Q. But it had to have happened 18 sometime before April 2017. Correct?</p> <p>19 A. Yes.</p> <p>20 Q. Did you have any sense of how 21 long the lead time was between Unomedical 22 beginning production of the new infusion sets and 23 them getting them over to Medtronic to put them 24 out onto the market?</p>
<p style="text-align: right;">Page 291</p> <p>1 A. Correct.</p> <p>2 Q. And that was in order to deplete 3 the supply that was already remaining before 4 beginning the production with the new material. 5 Correct?</p> <p>6 A. Correct.</p> <p>7 Q. Who made that decision, that you 8 should deplete the current stock of material 9 before beginning production with the new 10 material?</p> <p>11 A. Medtronic.</p> <p>12 Q. Who at Medtronic made that 13 decision?</p> <p>14 A. I don't remember exactly who held 15 that discussion.</p> <p>16 Q. Okay. Were you a part of it?</p> <p>17 A. At some point or the other, yes. 18 At least I presented this to -- to my management.</p> <p>19 Q. Okay. Did you concur in the 20 conclusion that you should deplete -- that 21 Unomedical should deplete the Emflon material 22 before beginning production with the new Porex 23 material?</p> <p>24 A. Yes, I did.</p>	<p style="text-align: right;">Page 293</p> <p>1 A. Yes, I did.</p> <p>2 Q. What was the lead time?</p> <p>3 A. So I just want to clarify. It's 4 not the beginning of production of the infusion 5 sets. It's the beginning of production of P-cap 6 assemblies.</p> <p>7 Q. Right. What I'm trying to 8 understand is --</p> <p>9 A. Which is a -- which is a step -- 10 which is a step previous to the -- to the 11 manufacturing of the infusion set. The regular 12 lead time for something like this is around four 13 months.</p> <p>14 Q. You mean -- what I'm trying to 15 understand is, is that Unomedical was expected to 16 begin producing the new P-caps with the membrane 17 in January of 2017. Correct?</p> <p>18 A. Correct.</p> <p>19 Q. And then you think the -- between 20 the manufacturing of the P-caps and the assembly 21 of the completed infusion set and return to 22 Medtronic, you think the lead time would be about 23 four months; is that correct?</p> <p>24 A. That is correct.</p>

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<p style="text-align: right;">Page 294</p> <p>1 Q. So that would indicate, if we 2 were working backward, that if the materials came 3 to market in April of 2017, that that would mean 4 that Unomedical began production of the P-caps in 5 January of 2017. Correct?</p> <p>6 A. Around January of 2017.</p> <p>7 Q. Okay. And you were aware that it 8 was in September of 2017 that it's a little more 9 than a year after the FDA approved the new 10 material that Medtronic issued a recall for the 11 infusion sets containing the Emflon material. 12 Correct?</p> <p>13 A. Correct.</p> <p>14 Q. Did you know that that recall was 15 coming?</p> <p>16 A. No.</p> <p>17 Q. Do you know why the recall wasn't 18 issued in 20 -- in April of 2017 when the new 19 infusion sets became available and on the market?</p> <p>20 A. No, I don't. I was not involved 21 in that project.</p> <p>22 MR. HAVERTY: Okay. Let's go off 23 the record for a second. I just want to 24 pull one thing up, and we're going to</p>	<p style="text-align: right;">Page 296</p> <p>1 consumables portion for Medtronic that these 2 infusion sets are set to be changed about every 3 three days. Correct?</p> <p>4 A. That's correct.</p> <p>5 Q. Okay. So that means that, if I 6 do the math correctly, a user would make about 7 121 infusion set changes in a year. Right? 8 Every three days, divided by 365, so that would 9 be 121 infusion set changes. Correct?</p> <p>10 A. That's a good approximation, 11 yeah.</p> <p>12 Q. So that would -- right. So that 13 would be 121 infusion set changes times 428,000 14 users. Right?</p> <p>15 A. Right.</p> <p>16 Q. That would mean in a given year, 17 there would be about just under 52,000 infusion 18 sets sold. Correct?</p> <p>19 A. 52 million.</p> <p>20 Q. Excuse me. 52 million.</p> <p>21 MS. MARTINEZ: Million.</p> <p>22 THE WITNESS: Million. The 23 actual number is closer to 65 --</p>
<p style="text-align: right;">Page 295</p> <p>1 wrap this up.</p> <p>2 THE VIDEOGRAPHER: We are now 3 going off the record, and the time is 4 4:16 p.m.</p> <p>5 - - -</p> <p>6 (A recess was taken from 4:16 7 p.m. to 7:24 p.m.)</p> <p>8 - - -</p> <p>9 THE VIDEOGRAPHER: We are now 10 going back on the record, and the time is 11 4:24 p.m.</p> <p>12 BY MR. HAVERTY:</p> <p>13 Q. Mr. Aleksandrovich, just a couple 14 of things, and hopefully I'm going to wrap this 15 up very quickly.</p> <p>16 You saw a little bit earlier when 17 we were talking about the original recall with 18 the "dear healthcare provider" letter back in 19 June of 2013, and they indicated that the 20 installed base of users was about 428,000 people.</p> <p>21 Do you remember that?</p> <p>22 A. I do.</p> <p>23 Q. Okay. And you're aware of the 24 fact because you run the disposables, the</p>	<p style="text-align: right;">Page 297</p> <p>1 BY MR. HAVERTY:</p> <p>2 Q. Okay.</p> <p>3 A. -- million units sold.</p> <p>4 Q. Okay.</p> <p>5 A. Yeah.</p> <p>6 Q. Okay. So it's 65 million units 7 sold.</p> <p>8 And it took approximately four 9 years from the time the temporary vent block 10 phenomenon was discovered until the new membrane 11 material went on the market for users. Correct?</p> <p>12 A. That is correct.</p> <p>13 Q. So if there is 65 million 14 infusion set changes a year and over four years, 15 that would mean that there were 260 million 16 infusion sets sold over that four-year period 17 that had that Emflon material in it. Correct?</p> <p>18 A. Correct.</p> <p>19 Q. And part of Medtronic's rationale 20 for its proprietary connector in its pump is so 21 that they could exclude other generic companies 22 from marketing infusion sets and reservoirs that 23 could be used with Medtronic pumps. Correct?</p> <p>24 MR. MERRELL: Objection to form.</p>

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<p style="text-align: right;">Page 298</p> <p>1 THE WITNESS: I cannot comment as 2 to the commercial strategy of Medtronic 3 as a company. 4 BY MR. HAVERTY: 5 Q. But we know they are looking at 6 65 million units a year of these infusion sets. 7 Correct? 8 A. Yes. 9 Q. Okay. Real quickly, if you could 10 take a look at Exhibit 53, please.</p> <p style="text-align: center;">- - -</p> <p>12 (Deposition Exhibit No. AA-53, 13 PowerPoint Slides, Bates stamped 14 MDT-BRACP-0081696 through 15 MDT-BRACP-0081716, was marked for 16 identification.)</p> <p style="text-align: center;">- - -</p> <p>18 BY MR. HAVERTY: 19 Q. Okay. Have you seen this chart 20 before, by the way? 21 A. Yes. 22 Q. Okay. When was the first time 23 you saw this? 24 A. A couple of days ago.</p>	<p style="text-align: right;">Page 300</p> <p>1 A. Yes. 2 Q. Okay. And if we keep going on, 3 each page adds another month. So in August of 4 2013, there are about 85 complaints under GA50. 5 Correct? 6 A. Correct. 7 Q. And then the next one is 8 September of 2013. It looks like it's about 62 9 complaints recorded? 10 A. Correct. 11 Q. And then October of 2013, it 12 looks like 59, just under 60? 13 A. Right. 14 Q. Okay. And by the way, just so 15 we're clear, this GA50 complaint code starts 16 right at the time where Medtronic had issued the 17 "dear healthcare provider" letter and the "dear 18 patient" letter warning about the getting insulin 19 on the reservoirs. Correct? 20 A. Correct. When that code was 21 specifically created for this. 22 Q. Right. So all of the data is 23 following that warning. Correct? 24 A. Correct.</p>
<p style="text-align: right;">Page 299</p> <p>1 Q. Okay. And did you understand 2 this to be an analysis of complaints and returns 3 related to the possible temp vent blockage 4 complaints that were now coded GA50? 5 A. Yes. But I wouldn't call it an 6 analysis. It's just a pure data collection. 7 Q. They were just raw numbers. 8 Correct? 9 A. Correct. 10 Q. But in any event, these -- all 11 these pages that go, beginning in June of 2013 12 and they continue on reporting both complaints 13 and returns coded under the GA50 possible temp 14 vent blockage complaints through May of 2014. 15 Correct? 16 A. Correct. 17 Q. It's about a year. Right? 18 A. Right. 19 Q. So if you look at June of 2013, 20 it looks like there are about 110 complaints 21 coded under the GA50 complaint code? 22 A. Correct. 23 Q. And then in July it looks like 24 there are about 85, 83 to 85 complaints?</p>	<p style="text-align: right;">Page 301</p> <p>1 Q. So now in November of 2013, we've 2 got recorded as 60 complaints. Correct? 3 A. Correct. 4 Q. And then December it's about 61. 5 Right? 6 A. Yes. 7 Q. And then in January, it looks 8 about 42, 43? 9 A. Right. 10 Q. And then in February, it's 40? 11 A. That's right. 12 Q. March, it's 41? 13 A. Correct. 14 Q. And then in April, it's 40 -- 15 about 45? 16 A. Yeah, about that. 17 Q. Okay. And then in May, it is 18 about 58 or so? 19 A. Correct. 20 Q. Now, I went and I added all those 21 up, and the number that I got was that in the 22 11-month period between June of 2013 and May of 23 2014, there were 750 complaints that were coded 24 under the GA50 possible temp vent blockage code.</p>

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<p style="text-align: right;">Page 302</p> <p>1 Does that seem -- does that seem 2 fair? 3 A. It does. 4 Q. Okay. So that would be contrary 5 to what you put in that note, that in your 6 extension request for the CAPA, that there were 7 no new reports of this phenomenon at the time. 8 Correct? 9 MR. MERRELL: Objection to form. 10 THE WITNESS: Okay. 11 BY MR. HAVERTY: 12 Q. Is that fair? 13 A. It's fair -- 14 Q. We know that -- 15 A. We didn't know that -- I meant 16 that there were no hospitalization or some 17 serious complications recorded. 18 Q. Okay. But we know that at a 19 minimum, there were about 750 complaints that 20 were coded under GA50? 21 A. Again, according to this -- to 22 this chart, without doing any analysis, yes. 23 Q. Right. But putting aside whether 24 there were hospitalizations or any injuries, per</p>	<p style="text-align: right;">Page 304</p> <p>1 THE WITNESS: Again, I cannot 2 conclude or make that statement based on 3 what I'm -- what I'm looking at, without 4 going into further details on the 5 analysis. 6 BY MR. HAVERTY: 7 Q. Okay. And that would be part of 8 the quality improvement team, I guess, would it 9 not? 10 A. That is correct. And speaking of 11 that, just to add to that, we -- quality 12 improvement team works in -- in percentages, and 13 signal needs to make it to a certain percentage 14 of failures as compared to units sold before it 15 becomes a real issue. 16 So if you look at the -- at the 17 right side of the chart, we're talking 18 about .001 -- between .001 and .00 -- at maximum 19 3 percent of units sold at 65 units -- at 65 20 million units a year. 21 Q. Right. And that -- I'm sure that 22 Medtronic thought that that was a very comforting 23 number. 24 However, if you're looking at 110</p>
<p style="text-align: right;">Page 303</p> <p>1 se, would the fact that there are 750 complaints 2 about this phenomenon of the insulin coming out 3 on its own indicate that the problem you were -- 4 that you had initially anticipated was still 5 there, that patients were getting insulin on the 6 reservoir caps and somehow contaminating the 7 connector caps. Correct? 8 A. Again, I cannot make that 9 assumption or conclusion judging from this data 10 without looking at actual complaints. 11 Q. But the GA50 code was 12 specifically created to capture those types of 13 complaints. Correct? 14 A. That is correct. 15 Q. Okay. So would you infer from 16 that that regardless of whether there are 17 hospitalizations or injuries, that the underlying 18 problem which the membrane redesign was intended 19 to correct was still there and some patients were 20 still doing the incorrect filling procedure, 21 regardless of whether they were injured or not? 22 A. Again -- 23 MR. MERRELL: Object -- objection 24 to the form.</p>	<p style="text-align: right;">Page 305</p> <p>1 complaints of this temporary vent blockage in 2 June of 2013, after the warnings had come out, 3 any one of those 110 could have resulted in an 4 injury or death. Right? 5 MR. MERRELL: Objection to form. 6 THE WITNESS: Can't -- can't make 7 that assumption, because I don't know 8 what was reported and what the patient 9 saw and how the report was taken and what 10 would be the result of the analysis of 11 that particular infusion set. 12 BY MR. HAVERTY: 13 Q. But all I'm saying is, is that if 14 a temporary vent blockage occurs, Medtronic was 15 aware that that could lead to the over-infusion 16 or under-infusion of insulin. Correct? 17 MR. MERRELL: Object to the form. 18 THE WITNESS: That is correct. 19 BY MR. HAVERTY: 20 Q. Okay. And that was the entire 21 purpose of redesigning the membrane material so 22 that you wouldn't get 110 complaints or 60 23 complaints in a month of this temporary vent 24 blockage phenomenon. You were going to eliminate</p>

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<p>1 that phenomenon. Correct?</p> <p>2 MR. MERRELL: Objection.</p> <p>3 BY MR. HAVERTY:</p> <p>4 Q. Or at least reduce it to the</p> <p>5 lowest possible.</p> <p>6 A. That we would eliminate that</p> <p>7 phenomenon, but that doesn't mean that we will</p> <p>8 stop receiving complaints.</p> <p>9 Q. What else could cause a temporary</p> <p>10 vent blockage phenomenon other than --</p> <p>11 A. Again -- so a person -- and I</p> <p>12 don't want to say anything bad about people, but</p> <p>13 I need to see -- me personally, I need to see the</p> <p>14 report exactly to understand whether it's a valid</p> <p>15 report or it's a misunderstanding of the issue or</p> <p>16 if it's a misrecording of an issue, a</p> <p>17 misclassification on the issue on the Medtronic</p> <p>18 side. That's possible as well.</p> <p>19 So again, that chart that we just</p> <p>20 discussed, it's completely inconclusive to me as</p> <p>21 part of the real failure and the real issue at</p> <p>22 hand.</p> <p>23 Q. And just -- and this probably</p> <p>24 will be my last question.</p>	<p>1 MR. MERRELL: I know. Because it</p> <p>2 may be hard to find it. Just a few</p> <p>3 questions.</p> <p>4 - - -</p> <p>5 EXAMINATION</p> <p>6 - - -</p> <p>7 BY MR. MERRELL:</p> <p>8 Q. When did you begin your</p> <p>9 involvement with the temporary vent block CAPA</p> <p>10 again?</p> <p>11 A. Around summer -- spring/summer of</p> <p>12 2013. I don't remember exactly when.</p> <p>13 Q. And how many years ago was that</p> <p>14 from today?</p> <p>15 A. Five already.</p> <p>16 Q. Do you recall all of the details</p> <p>17 from the CAPA sitting here today four, five years</p> <p>18 later?</p> <p>19 A. No. I can't possibly remember</p> <p>20 everything.</p> <p>21 Q. Okay. Was the temporary -- was</p> <p>22 the temporary vent blockage issue a result of a</p> <p>23 design problem?</p> <p>24 A. No, it was not.</p>
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<p>1 Are you aware one way or the</p> <p>2 another of whether the help line employees were</p> <p>3 trained on utilizing this new GA50 code for the</p> <p>4 precise purpose of trending what this phenomenon</p> <p>5 was -- how it was occurring out in actual use?</p> <p>6 A. I'm sure there were trained to</p> <p>7 some extent. I don't know exactly the extent of</p> <p>8 the training and the detail of the training.</p> <p>9 Again, that is out of realm of my responsibility,</p> <p>10 and I cannot answer for that department.</p> <p>11 MR. HAVERTY: Right. Mr.</p> <p>12 Aleksandrovich, I don't have anything</p> <p>13 further for you. Thank you.</p> <p>14 THE WITNESS: Thank you.</p> <p>15 MR. MERRELL: I have a few</p> <p>16 questions. I assume Marlene doesn't have</p> <p>17 any questions?</p> <p>18 MS. GOLDENBERG: Not for now, no.</p> <p>19 MR. MERRELL: Okay.</p> <p>20 THE WITNESS: Are we going to</p> <p>21 refer to any of this?</p> <p>22 MR. MERRELL: We may. If it's</p> <p>23 not organized, you can use my copy.</p> <p>24 THE WITNESS: Sorry.</p>	<p>1 Q. Were --</p> <p>2 A. Or it is not.</p> <p>3 Q. Was the temporary vent block</p> <p>4 issue a result of a design flaw with the -- with</p> <p>5 the infusion set?</p> <p>6 A. No, it's not.</p> <p>7 MR. HAVERTY: Objection.</p> <p>8 Are you -- Cliff, are you</p> <p>9 producing him as an expert witness?</p> <p>10 MR. MERRELL: I haven't decided</p> <p>11 yet, but I'm just simply asking the</p> <p>12 questions as it stands now.</p> <p>13 What ws --</p> <p>14 MR. HAVERTY: Well, I think --</p> <p>15 cliff, let me note my objection.</p> <p>16 If you intend to qualify him as</p> <p>17 an expert witness, then I'm entitled to a</p> <p>18 report.</p> <p>19 MR. MERRELL: Okay. I understand</p> <p>20 your position.</p> <p>21 BY MR. MERRELL:</p> <p>22 Q. What was the temporary vent block</p> <p>23 issue a result of?</p> <p>24 A. An incorrect filling process of</p>

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<p style="text-align: center;">Page 310</p> <p>1 reservoir, which is basically advertently or not 2 advertently not following the instruction.</p> <p>3 Q. And has that been documented in 4 the various documents we looked through today 5 from the CAPA?</p> <p>6 A. Yes, it was.</p> <p>7 Q. And as a result of the improper 8 reservoir filling, did Medtronic and did you, 9 were you looking for a potential design solution 10 to address this user error?</p> <p>11 A. Yes.</p> <p>12 Q. And you testified earlier that -- 13 about the instructions and the warnings alone 14 were not a good enough solution for you with 15 respect to the CAPA.</p> <p>16 Can you explain that?</p> <p>17 A. Right. Not necessarily. I may 18 have used the wrong term. Not that they're not 19 good enough, but we wanted to follow through and 20 create something even more robust that will not 21 only prevent but eliminate the potential of 22 failure.</p> <p>23 Q. And why is that?</p> <p>24 A. Because as a company, Medtronic,</p>	<p style="text-align: center;">Page 312</p> <p>1 preventative?</p> <p>2 A. No, I wouldn't.</p> <p>3 Q. And with respect to the material 4 change in the membrane, would you characterize 5 that as a corrective or preventative measure?</p> <p>6 A. No, I wouldn't. They all have 7 the ultimate goal, the same ultimate goal.</p> <p>8 Q. You testified that it took I 9 guess between three-and-a-half and four years to 10 change the membrane material; is that correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Did you have any concerns that it 13 took three-and-a-half years to four years to 14 change the membrane?</p> <p>15 A. No.</p> <p>16 Q. And can you explain that?</p> <p>17 A. Yes. Because the warnings that 18 we issued and the steps that we took with those 19 warnings to our understanding and best knowledge 20 were significant enough and robust enough to 21 carry us through the design change.</p> <p>22 Q. And did you believe that those 23 efforts were sufficient to carry through the 24 design change?</p>
<p style="text-align: center;">Page 311</p> <p>1 our patients are of the utmost concern to us, and 2 we make them as safe as possible.</p> <p>3 Q. And there's a testimony earlier, 4 questions earlier about CAPA and there being a 5 corrective and then preventative component of it.</p> <p>6 Do you recall that?</p> <p>7 A. I do.</p> <p>8 Q. Do you compartmentalize the 9 various actions taken in the CAPA between a 10 corrective versus preventative action?</p> <p>11 A. No, I don't.</p> <p>12 Q. Can you explain that?</p> <p>13 A. A CAPA is merely a name of a 14 process that's intended to improve upon 15 something, and any actions taken in there are all 16 towards the success, but that's ultimately 17 success of the project. And I wouldn't 18 categorize them one are -- some are more 19 important, some are less, some are corrective, 20 some are preventative. It's all -- it's all 21 leading to.</p> <p>22 Q. So for example, with the 23 warnings, the notification, would you categorize 24 those just in a specific bucket of corrective or</p>	<p style="text-align: center;">Page 313</p> <p>1 A. Yes, we did.</p> <p>2 Q. Can you explain why did it take 3 three-and-a-half years to make the membrane 4 change from the beginning of the CAPA?</p> <p>5 A. It's due to multiple reasons. So 6 first, obviously, we had material. We selected 7 material that looked good at the beginning and 8 fulfilled the design requirements at the 9 beginning but proved to be not very usable in a 10 high volume manufacturing. Also, since we are in 11 the very regulated industry, we have to follow 12 certain step and take certain -- certain 13 precautions and certain documentation steps and 14 sequences, sometimes directed by government that 15 just cannot simply do -- get done faster than 16 they can.</p> <p>17 Q. Can you take a look at Exhibit 2 18 on page 8 again.</p> <p>19 A. Yes.</p> <p>20 Q. And if you look on page 8 through 21 9, are there 16 various action steps and phases 22 that are listed here?</p> <p>23 A. Yes, there are 16.</p> <p>24 Q. And can you explain, are these</p>

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<p>1 required for you to be able to make this decision 2 change for the P-cap?</p> <p>3 A. Yes, they are.</p> <p>4 Q. And why is that?</p> <p>5 A. Again, because we need to adhere 6 to certain procedures and certain rules and 7 regulations and also need to do a fair amount of 8 testing and other activities that are involved.</p> <p>9 Q. In replacing the material 10 membrane for the P-cap, is there a risk or 11 concern that the solution could actually cause 12 more problems than the original membrane?</p> <p>13 MR. HAVERTY: Objection.</p> <p>14 THE WITNESS: No, there is not.</p> <p>15 There is no such concern.</p> <p>16 BY MR. MERRELL:</p> <p>17 Q. And why is that?</p> <p>18 A. Because we proved by it testing 19 and verification that there is not.</p> <p>20 Q. To be able to eliminate that 21 concern, did you have to go through these 22 processes?</p> <p>23 A. Yes, we did.</p> <p>24 Q. And are these processes part of</p>	<p>1 Q. And in the Lot 8 CAPA, did that 2 address the failure mechanism there?</p> <p>3 A. For the -- identified for Lot 8?</p> <p>4 Q. Yes.</p> <p>5 A. Yes, it did.</p> <p>6 Q. Was the temporary vent blockage 7 CAPA that you worked on, was that an important 8 project for Medtronic?</p> <p>9 A. It was.</p> <p>10 Q. Did Medtronic expend a 11 significant amount of resources on that CAPA?</p> <p>12 A. Every required resource was at my 13 disposal.</p> <p>14 Q. Why is that?</p> <p>15 A. Because it was important to 16 patient safety ultimately.</p> <p>17 Q. Has the FDA ever been critical at 18 all regarding the amount of time it took to 19 implement the membrane material change under the 20 CAPA?</p> <p>21 A. Not that I'm aware of.</p> <p>22 Q. You discussed different materials 23 that were evaluated for changing the membrane for 24 the P-cap.</p>
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<p>1 the quality system at Medtronic?</p> <p>2 A. That is correct.</p> <p>3 Q. Is that quality system required 4 by FDA regulations?</p> <p>5 A. Among other things.</p> <p>6 Q. You were asked earlier about Lot 7 8.</p> <p>8 Was Lot 8 and then the temporary 9 vent block CAPA you worked on, was it the same 10 failure mode?</p> <p>11 A. They were the same failure -- 12 they produced the same failure mode, yes.</p> <p>13 Q. Was it the same failure 14 mechanism?</p> <p>15 A. Not at all.</p> <p>16 Q. Can you explain that?</p> <p>17 A. Yes. Lot 8 failure mechanism was 18 connected to a manufacturing process utilized 19 back at that time with the production of silicone 20 oil for lubrication of the inside of the P-cap. 21 And once that oil was removed, the problem went 22 away; whereas temporary vent block failure 23 mechanism has to do with accidental introduction 24 of any fluid onto the P-cap membrane.</p>	<p>1 What was the original choice for 2 Medtronic?</p> <p>3 A. The original was a Versapor 450R 4 material manufactured by Pall Corporation.</p> <p>5 Q. And why ultimately did you have 6 to switch to a different choice?</p> <p>7 A. Because despite the fact that it 8 produced acceptable results on the functional 9 side, it demonstrated prohibitive -- prohibitive 10 behavior to be used in the high volume 11 manufacturing environment.</p> <p>12 Q. And would that -- does that 13 indicate that there could have been quality 14 issues if you tried to manufacture it?</p> <p>15 A. Yes.</p> <p>16 Q. You -- as I understand, did you 17 identify three -- ultimately three potential 18 materials that were tested?</p> <p>19 A. That is correct.</p> <p>20 Q. And how would you characterize 21 the wet flow of those three potential options?</p> <p>22 A. As acceptable.</p> <p>23 Q. And was there a specification you 24 were looking at and measuring them against?</p>

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<p>1 A. I don't remember what came first, 2 the wet flow spec or the material themselves that 3 were tried.</p> <p>4 Q. Okay. But did you find that 5 those three materials, that they met the 6 requirements for Medtronic?</p> <p>7 A. Yes, absolutely.</p> <p>8 Q. You were asked earlier about the 9 continuation of manufacturing the membrane 10 using -- utilizing the Emflon membrane. 11 Do you recall that?</p> <p>12 A. Yes.</p> <p>13 Q. And as I understand it, the 14 manufacturer utilizing the newer membrane, that 15 began in January of 2017?</p> <p>16 A. Correct.</p> <p>17 Q. Did you testify you were involved 18 in that decision?</p> <p>19 A. I was not involved in that 20 decision. I provided information.</p> <p>21 Q. But you testified that you 22 concurred with that decision?</p> <p>23 A. Correct.</p> <p>24 Q. Why is that?</p>	<p>1 A. Percentage-wise?</p> <p>2 Q. Yes.</p> <p>3 A. Less than half -- than 4 significantly less than half a percent.</p> <p>5 Q. Without the benefit of the 6 individual complaints, are you able to draw any 7 conclusions based on this data?</p> <p>8 A. No, I cannot.</p> <p>9 MR. MERRELL: Those are all the 10 questions I have.</p> <p>11 MS. MARTINEZ: I have one 12 question. 13 - - - 14 EXAMINATION 15 - - -</p> <p>16 BY MS. MARTINEZ: 17 Q. Mr. Aleksandrovich, you were 18 asked about certain things that Unomedical did in 19 connection with Medtronic's decision to change 20 the membrane to a Porex membrane. 21 Did Unomedical act with the due 22 diligence that you expected and do everything 23 that Unomedical was asked?</p> <p>24 A. Absolutely.</p>
<p>1 A. Because it was safe enough 2 to deplete the material given the precautions -- 3 (Court reporter clarification.)</p> <p>4 BY MR. MERRELL: 5 Q. Why did you concur with that -- 6 why did you concur with that decision?</p> <p>7 A. Because it felt -- it felt safe 8 to continue depleting and using the Emflon 9 material due to the steps that we as a company 10 took to prevent the potential failure in the 11 field with warnings and IFUs and such.</p> <p>12 Q. You were asked just a few 13 questions at the end regarding Exhibit 53. 14 Do you recall that?</p> <p>15 A. I do.</p> <p>16 Q. And there is a -- there's a list 17 of numerically the number of GA50 complaints at 18 the end.</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. How would you characterize the 22 rate of those complaints?</p> <p>23 A. As extremely low.</p> <p>24 Q. What was the range of the rates?</p>	<p>1 MR. HAVERTY: Objection, 2 objection.</p> <p>3 MS. MARTINEZ: Thank you.</p> <p>4 MR. HAVERTY: Note my objection. 5 You're asking him expert witness -- do 6 you want him to produce a report, Ileana? 7 I move to strike that as an expert --</p> <p>8 MS. MARTINEZ: Again, this is -- 9 MR. HAVERTY: I move --</p> <p>10 BY MS. MARTINEZ: 11 Q. Just for the record, let me 12 repeat again, you dealt with Unomedical and asked 13 Unomedical to do certain things in connection 14 with Medtronic's decision to change the current 15 membrane or the then-existing membrane to a Porex 16 membrane. 17 I'm asking you as an employee of 18 Medtronic that dealt with Unomedical, did 19 Unomedical exhibit due diligence in its actions 20 and do everything that you asked --</p> <p>21 MR. HAVERTY: Objection. 22 MR. MERRELL: -- Unomedical to 23 do? 24 THE WITNESS: Yes, they did.</p>

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<p style="text-align: right;">Page 322</p> <p>1 MR. HAVERTY: Objection. Again, 2 I move to strike. That's an expert 3 witness question. 4 Ileana, if you want to ask him -- 5 by the way, Marlene, if you want to jump 6 in on this. 7 If you want to ask him whether or 8 not they did everything he expected them 9 to do, then that's a different question, 10 but you just asked him a standard of care 11 question. 12 MS. MARTINEZ: I didn't. No, no. 13 I did ask him what -- 14 MR. HAVERTY: Exercising -- 15 MS. MARTINEZ: -- if they did 16 everything that he expected them to do. 17 THE WITNESS: Yes, they did. 18 MR. HAVERTY: No. You asked 19 whether they acted with due diligence. 20 Ileana, you asked -- 21 MS. GOLDENBERG: And Ileana, I'll 22 just note that Kevin has been objecting 23 on behalf of both of us, even though 24 technically you're only appearing in the</p>	<p style="text-align: right;">Page 324</p> <p>1 you believe they were robust, and they were -- 2 they were substantial enough to prevent the 3 problem. Correct? 4 A. Correct. 5 Q. And as we saw from that email 6 from the FDA, the FDA did not concur with that 7 assessment, did they? 8 MR. MERRELL: Objection to form. 9 THE WITNESS: Okay. I'll agree 10 to that. 11 BY MR. HAVERTY: 12 Q. And you want to talk about -- you 13 talked about the distinction between the failure 14 mode and the failure mechanism between the Lot 8 15 and the temporary vent block. 16 In fact, the mechanism of failure 17 is exactly the same. It's the blocking of the 18 vents, is it not? 19 MR. MERRELL: Objection to form. 20 THE WITNESS: That's what you're 21 referring -- in this case, in our 22 industry, judging -- going from the rules 23 how we do the failure mode and effect 24 analysis, that's the failure effect.</p>
<p style="text-align: right;">Page 323</p> <p>1 Eklund case, so that objection applies to 2 both. 3 BY MS. MARTINEZ: 4 Q. Let me ask it again, just so the 5 record is clear. 6 In your dealings with Unomedical 7 in connection with Medtronic's decision to change 8 the then-existing membrane in the P-cap to a 9 Porex membrane, did Unomedical do everything that 10 you asked? 11 A. Yes, they did. 12 Q. Did they do it in the time frame 13 that you asked them to do it? 14 A. For the most part they did. 15 MS. MARTINEZ: Okay. Thank you. 16 MR. HAVERTY: I just have a 17 couple follow-ups, Mr. Aleksandrovich. 18 - - - 19 EXAMINATION 20 - - - 21 BY MR. HAVERTY: 22 Q. You said that you believe that 23 the warnings that were put in place after the 24 temporary vent block process was found were --</p>	<p style="text-align: right;">Page 325</p> <p>1 Blocked membrane is a failure effect. 2 BY MR. HAVERTY: 3 Q. Isn't the failure effect the 4 over-infusion or under-infusion of insulin? 5 That's the failure effect. Correct? 6 MR. MERRELL: Objection to form. 7 THE WITNESS: On the system 8 level, maybe. But if we're talking only 9 about the P-cap, it's the blocked 10 membrane. 11 BY MR. HAVERTY: 12 Q. Right. And that's the mechanism 13 by which the failure effect can occur, is the 14 membrane gets blocked, and that can cause an 15 over-infusion or under-infusion of insulin, 16 whether it's from excess silicone oil or from 17 insulin. Correct? 18 A. Okay. Yes. 19 Q. The only real difference between 20 the two is one was an identifiable manufacturing 21 defect while the other one deals with a 22 vulnerability in the design of the membrane in 23 the connector cap, the venting membrane. 24 Correct?</p>

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<p style="text-align: right;">Page 326</p> <p>1 MR. MERRELL: Objection to form. 2 THE WITNESS: No, I don't agree 3 with that. One was the identifiable 4 manufacturing process issue. The other 5 one is -- we can call it a human factor 6 issue.</p> <p>7 BY MR. HAVERTY: 8 Q. Right. But my point is -- 9 A. But it's not -- it's not a design 10 issue.</p> <p>11 Q. Well, it is a design issue 12 because that's exactly what you did in this CAPA, 13 was you redesigned that membrane material to 14 prevent this hazard. Correct?</p> <p>15 A. We redesigned to -- to provide a 16 mistake-proof, if you will, ability for users.</p> <p>17 Q. Right. Because you know that 18 humans can make mistakes. And so the hierarchy 19 of risk mitigation is to design out a hazard if 20 you can. Correct?</p> <p>21 A. That is correct. But the hazard 22 occurred in this case due to the human factor 23 interaction only.</p> <p>24 Q. Right. But if the membrane could</p>	<p style="text-align: right;">Page 328</p> <p>1 proved that it was feasible to have a membrane 2 that could remain gas permeable, even if 3 contacted by fluid. Correct?</p> <p>4 A. Potentially, yes.</p> <p>5 Q. Well, that's what you 6 represented --</p> <p>7 MS. MARTINEZ: Kevin we're 8 getting a --</p> <p>9 MR. HAVERTY: Okay. I just have 10 one quick question.</p> <p>11 BY MR. HAVERTY: 12 Q. You believe that your mitigation 13 prior to the putting the redesigned membrane on 14 the market was good enough.</p> <p>15 Would you agree with me then that 16 if someone suffered an injury from an 17 over-infusion of insulin that could be traced 18 back to a blocked vent situation, that that would 19 prove that your system of risk mitigation was not 20 adequate?</p> <p>21 MR. MERRELL: Objection to form.</p> <p>22 THE WITNESS: It's -- it's 23 speculation, so we have -- we have 24 proof -- we have proof statistical that</p>
<p style="text-align: right;">Page 327</p> <p>1 remain gas permeable, the human factors aspect of 2 it wouldn't have mattered. So it was a design 3 issue, was it not?</p> <p>4 A. No, it was not.</p> <p>5 Q. Okay. So why did you 6 undertake to --</p> <p>7 A. It's not considered a design 8 issue.</p> <p>9 Q. Okay. But you will agree with me 10 that what you did in the CAPA was you redesigned 11 the membrane. Correct?</p> <p>12 A. Yes, yes. I agree with that.</p> <p>13 Q. Okay. And therefore, what you 14 did was you proved that it was feasible to design 15 out this hazard of the over-infusion or 16 under-infusion of insulin due to vent block, the 17 blocked vents. Correct?</p> <p>18 MR. MERRELL: Objection to form.</p> <p>19 THE WITNESS: Not very clear on 20 the question.</p> <p>21 BY MR. HAVERTY: 22 Q. By virtue of the fact that you 23 were able to achieve a redesign, put it into 24 manufacturing and put it out on the market, you</p>	<p style="text-align: right;">Page 329</p> <p>1 it hasn't occurred.</p> <p>2 BY MR. HAVERTY: 3 Q. Well, what you have are 4 complaints that are received by Medtronic. If 5 someone was injured by this and didn't report it 6 to Medtronic, you wouldn't know about it.</p> <p>7 Correct?</p> <p>8 A. That is correct.</p> <p>9 MR. HAVERTY: That's all I have.</p> <p>10 Thank you.</p> <p>11 THE WITNESS: Thank you.</p> <p>12 MS. GOLDENBERG: I just have a 13 few questions, if you don't mind. Sorry. 14 I'll keep it close. I know you guys are 15 getting a signal from the videographer.</p> <p>16 - - -</p> <p>17 EXAMINATION</p> <p>18 - - -</p> <p>19 BY MS. GOLDENBERG: 20 Q. Mr. Aleksandrovich, my name is 21 Marlene Goldenberg. We haven't had a chance to 22 formally meet yet, but I'm here on behalf of the 23 plaintiffs in this case also.</p> <p>24 And I believe that you testified</p>

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<p style="text-align: center;">Page 330</p> <p>1 that safety is the most important thing at 2 Medtronic; is that right? 3 A. That is correct. 4 Q. And that's more important than 5 profits. Right? 6 A. Of course, yes. (Court reporter clarification.) 8 MS. GOLDENBERG: My question was 9 that safety is more important than 10 profits, and he agreed. 11 BY MS. GOLDENBERG: 12 Q. Mr. Aleksandrovich, I apologize, 13 we need a verbal answer. 14 A. Yes, it is, of course. 15 Q. Okay. And in putting patient 16 safety first, that means complying with all 17 regulatory requirements. Right? 18 A. Right. 19 Q. But even beyond that, it means 20 that, you know, you don't have to wait for the 21 FDA to catch a problem, that Medtronic should be 22 proactive when they're aware that something is 23 wrong that could compromise patient safety. 24 Right?</p>	<p style="text-align: center;">Page 332</p> <p>1 injury is not a regular complaint. 2 BY MR. HAVERTY: 3 Q. These 700 -- these roughly 700 4 complaints that came in were all specific to the 5 new code that had been created after the letter 6 went out to patients. Right? 7 A. They were recorded under that 8 code, yes. 9 Q. Okay. And in order to be 10 recorded under that code, health line 11 representatives had to have been trained to 12 recognize that that was the effect that was 13 occurring. Right? 14 A. Right. 15 MR. MERRELL: Objection to form. 16 THE WITNESS: Probably. 17 BY MR. HAVERTY: 18 Q. Okay. And if those complaints 19 are still recorded in the reports that we were 20 referring to earlier, those complaints presumably 21 had been validated by someone working at the help 22 line or one of their supervisors. Right? 23 A. Presumably, yes. 24 Q. Okay. And Medtronic indicated in</p>
<p style="text-align: center;">Page 331</p> <p>1 MR. MERRELL: Objection to form. 2 THE WITNESS: Absolutely. 3 BY MS. GOLDENBERG: 4 Q. Okay. And you also testified 5 that the number of complaints that had been 6 reported after the 2013 warning letter went out 7 to patients was an acceptable level; is that 8 right? 9 MR. MERRELL: Objection, form. 10 THE WITNESS: Yeah. Acceptable 11 to the method that we measured them with, 12 yes. 13 BY MS. GOLDENBERG: 14 Q. Okay. And what is the threshold 15 of how many severe injuries or death is 16 acceptable to Medtronic? 17 MR. MERRELL: Objection to form. 18 THE WITNESS: So we're not 19 talking about severe injuries. None of 20 these resulted in severe injuries. It 21 would have been treated completely 22 different. And to answer your question, 23 I am not sure what a threshold for 24 certain failures, but again, severe</p>	<p style="text-align: center;">Page 333</p> <p>1 its dear patient and "dear doctor" letters that 2 the most likely effect of the over-delivery or 3 under-delivery of insulin was hyper- or 4 hypoglycemia. Right? 5 A. Correct. 6 Q. And you testified earlier that 7 nothing good can come from an over-delivery of 8 insulin. Right? 9 A. I'm sorry, I wasn't -- you broke 10 up a little bit. 11 Q. I believe you testified earlier 12 that nothing good can come from an over-delivery 13 of insulin; is that right? 14 A. I can hear nothing good can come? 15 Yes. I said that. Of course, yes. 16 Q. I'm sorry. 17 Okay. And so I guess what I'm 18 wondering is how is Medtronic making -- strike 19 that. 20 What is Medtronic's definition of 21 a serious injury? 22 A. I don't know. I can't answer 23 that question. 24 Q. Okay. But suffice it to say,</p>

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<p style="text-align: right;">Page 334</p> <p>1 your position is that these roughly 700 cases 2 were not classified to be serious despite the 3 fact that nothing good can come from an 4 over-delivery of insulin?</p> <p>5 A. To what I know at this point 6 without looking at each report individually, yes.</p> <p>7 Q. Okay. Switching topics a little 8 bit, you had testified that at one point, 9 Medtronic manufactured a reservoir that would go 10 with a Luer Lock infusion set that was not made 11 by Medtronic; is that right?</p> <p>12 A. That's not what I said. I said 13 Medtronic manufactured a reservoir with a Luer 14 Lock interconnection, but the intent of course is 15 to use it with the infusion sets manufactured by 16 Unomedical and marketed by Medtronic with Luer 17 Lock connection as well.</p> <p>18 Q. Okay. Could a different infusion 19 set have been used with that reservoir?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And was that type of 22 reservoir available in 2014?</p> <p>23 A. I believe so.</p> <p>24 Q. Was it available in 2016?</p>	<p>1 Q. Okay. So you're not holding 2 yourself out to be an expert in warnings?</p> <p>3 A. Not at all.</p> <p>4 MS. GOLDENBERG: Okay. Those are 5 all the questions I have. Thank you for 6 your time.</p> <p>7 THE WITNESS: Thank you. Thank 8 you very much.</p> <p>9 MR. HAVERTY: I guess we're 10 getting the bum's rush.</p> <p>11 THE VIDEOGRAPHER: That 12 concludes -- okay? This concludes the 13 video deposition of Anatoly 14 Aleksandrovich consisting of four DVDs. 15 We are now going off the record, and the 16 time is 5:00 p.m.</p> <p>17 (Deposition adjourned at 18 approximately 5:00 p.m.)</p>
<p style="text-align: right;">Page 335</p> <p>1 A. I am not sure when we stopped 2 manufacturing that reservoir.</p> <p>3 Q. While the new P-cap was being 4 designed, was there ever any thought given to 5 advising patients to use different infusion sets?</p> <p>6 A. I cannot answer to that question, 7 but it is impossible to use a different infusion 8 set with a Paradigm pump or NGP pump.</p> <p>9 Q. Okay. So let me just make sure I 10 understand, because I may be misconstruing what 11 you're saying.</p> <p>12 The reservoir that works with the 13 Luer Lock, that would allow other infusion sets 14 not being manufactured by Medtronic to be used 15 with that reservoir. Right?</p> <p>16 A. Correct.</p> <p>17 Q. And that combination products 18 could have been used with the Paradigm pump?</p> <p>19 A. No, it could not have.</p> <p>20 Q. Okay. I understand.</p> <p>21 You testified that you didn't 22 really have much to do with the FDA or regulatory 23 issues. Right?</p> <p>24 A. Correct.</p>	<p>1 Page 337</p> <p>1 CERTIFICATE</p> <p>5 I HEREBY CERTIFY that the witness 6 was duly sworn by me and that the deposition is a 7 true record of the testimony given by the witness.</p> <p>8 It was requested before 9 completion of the deposition that the witness, 10 ANATOLY ALEKSANDROVICH, have the opportunity to 11 read and sign the deposition transcript.</p> <p>14 ANN MARIE MITCHELL, a Federally 15 Approved Certified Realtime 16 Reporter, Registered Diplomate 17 Reporter, Registered Merit Reporter and 18 Notary Public</p> <p>19 (The foregoing certification of 20 this transcript does not apply to any 21 reproduction of the same by any means, unless 22 under the direct control and/or supervision of 23 the certifying reporter.)</p>

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<p style="text-align: right;">Page 338</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections.</p> <p>5 You should state the reason in the appropriate</p> <p>6 space on the errata sheet for any corrections</p> <p>7 that are made.</p> <p>8 After doing so, please sign the</p> <p>9 errata sheet and date it.</p> <p>10 You are signing same subject to</p> <p>11 the changes you have noted on the errata sheet,</p> <p>12 which will be attached to your deposition.</p> <p>13 It is imperative that you return</p> <p>14 the original errata sheet to the deposing</p> <p>15 attorney within thirty (30) days of receipt of</p> <p>16 the deposition transcript by you. If you fail to</p> <p>17 do so, the deposition transcript may be deemed to</p> <p>18 be accurate and may be used in court.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: left;">Page 340</p> <p>1</p> <p>2 ACKNOWLEDGMENT OF DEONENT</p> <p>3</p> <p>4 I, _____, do</p> <p>5 hereby certify that I have read the foregoing</p> <p>6 pages, 1 - 340, and that the same is a correct</p> <p>7 transcription of the answers given by me to the</p> <p>8 questions therein propounded, except for the</p> <p>9 corrections or changes in form or substance, if</p> <p>10 any, noted in the attached Errata Sheet.</p> <p>11</p> <p>12</p> <p>13</p> <p>14 ANATOLY ALEKSANDROVICH DATE</p> <p>15</p> <p>16</p> <p>17 Subscribed and sworn</p> <p>18 to before me this</p> <p>19 ____ day of _____, 20 ____.</p> <p>20 My commission expires: _____</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: left;">Page 339</p> <p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>	

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